Is South Africa ready for a national Electronic Health Record (EHR)?

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Abstract

Background

eHealth Strategies in countries have shown a trend that countries are moving to Electronic Health Records(EHR). EHR implementation is expected to produce benefits for patients, professionals, organisations, and the population as a whole. The use of some format of an Electronic Health Record is used by many countries and others are in the implementation or planning phases. South Africa has kicked of the project to implement a national EHR as part of the national eHealth Strategy. This study aims to analyse the key success factors from other EHR implementation projects and evaluate if South Africa is ready to implement an EHR.

Methods

This research study will use a qualitative case study research method approach, to analyse the data and debate an opinion to answer if South Africa is ready for a National Electronic Health record.

Results

Analysis of the following country case studies; Australia, Belize, Canada, Denmark, Estonia, Hong Kong, Netherlands and Sweden will be tabled under the subcategories to compare the different country parameters with one another to establish key success factors.

Conclusions

The key success factors can form the basic blueprint objectives in a guideline for not only the South African implementation of an EHR but any national initiative. As seen in the results the case countries had several ways to achieve the same outcome. This highlights the fact that there is not a right or wrong but a requirement to contextualise the factors in the country environment.

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Chapter 1 Study Introduction

The use of Electronic Health Records (EHR) in the health care industry is currently supported in many countries including countries in Europe and North America. Each Country that considered implementing an EHR reviewed different factors and areas to ensure that they eliminate the barriers before starting an implementation project.

South Africa kicked off the project to initialise a national EHR during 2002, as part of the eHealth Strategy for South Africa introduced by the National Department of South Africa. A complete content of the proposed eHR.ZA is included in Appendix 2. This research will review the key success factors of previous implementation attempts by other countries and measure it against the South African environment.

The first EHRs began to appear in the 1960s. Early projects had significant technical and programmatic issues, including non-standard vocabularies and system interfaces, which remain implementation challenges today. But they lead the way, and many of the ideas they pioneered and some of the technology are still used today. (National Institute of Health National Centre for Research resources, 2006)

EHRs differ between institutions and even countries due to not only the barriers but also the needs of the respective institutions and countries. An EHR can include information such as observations, laboratory tests, diagnostic imaging reports, treatments, therapies, drugs administered, patient identifying information, legal permissions, and allergies.

Whatever the type of electronic health record decided upon the health information contained in it must be organized primarily to support continuing, efficient, and quality healthcare. It must also continue to meet legal, confidentiality, and retention requirements of the patient, the attending health professional and the healthcare institution/country. (World Health Organization, 2006)

Background

Over the last two decades multiple countries and institutions attempted to implement electronic health records (EHR), at either national or institutional level. However, the type and extent of electronic health records vary and what one country call an EHR may not be the same as the next.

For the purpose of this research paper we would define an Electronic Health Record (EHR) as follow:

"An electronic health record (EHR) (also electronic patient record (EPR) or computerised patient record) is an evolving concept defined as a systematic collection of electronic health information about individual patients or populations. It is a record in digital format that is capable of being shared across different health care settings, by being embedded in network-connected enterprise-wide information systems. Such records may include a whole range of data in comprehensive or summary form, including demographics, medical history, medication and allergies, immunization status, laboratory test results, radiology images, and billing information." (World Health Organization, 2006)

Its purpose can be understood as a complete record of patient encounters that allows the automation and streamlining of the workflow in health care settings and increases safety through evidence-based decision support, quality management, and outcomes reporting.

In May 2002 South Africa joined the list and initiated the project to implement a National Electronic Health Record. In May 2002 a workshop was held in which three working groups were formed namely:

- Laboratory System Working Group
- Evaluation of the Health Information System and
- The Electronic Health Record Working Group

The South African EHR initiative started in September 2003 in which a workshop was held, in order to standardise on the National Electronic Health Record (EHR)

concept. However the EHR initiative was only published in 2007 (National Publisher, 2007)

The workshop report has formed the basis of the National strategic Framework for EHR in South Africa. During the workshop the department of health defined the goals of the Electronic Health Record as:

- To integrate health record systems in the country by bringing together all the different health information systems facilitating access to health records within a province and across provinces.
- To develop a population health care base.
- To Improve Governance, Planning Administration and Management of Health systems at both national and provincial level.
- To improve the efficiency of health service delivery both personal care and public health services
- To enable national monitoring and evaluation of health trends
- Achieve comprehensive privacy and confidentiality requirements of the citizens

And the objectives:

- Integrate different episodes into individual longitudinal records
- Track patients for continuing health care
- Reduce medical errors
- Provide easy access to records
- Improve referral system
- Monitor health care behaviours
- Promote transparency and efficiency
- Improve surveillance methods (Khumisi et al., 2008)

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Problem Statement

The aim of this research is to use case studies of institutions/countries that have attempted and are currently attempting to implement electronic health record systems, with a view of finding best practice to EHR adoption. It is also the intention of the study to evaluate if South Africa is ready to implement a national EHR.

Sub-Problem 1:

What are the key success factors in EHR implementation?

Sub-Problem 2:

Evaluate the challenges for the South African environment for the implementation of an EHR

Objectives

- To analyse the key success factors in EHR implementation.
- To compare the key success factors above from various country implementations to establish is a blue print for EHR implementation can be achieved.
- To review the possible barriers for implementing an EHR in South Africa.

Importance of the study

The global health care industry is focussed on the issue of patient safety and more institutions/countries have or started to implement a form of an EHR. The implementations within institutions have a high success rate because of the controlled environment in which the EHR is implemented, but implementing an EHR at national level changes the odds.

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It is important to establish what your expectations are relating to the EHR. There are many macro and micro environment factors than need to be considered when implementing an EHR.

The benefits for an EHR was listed and discussed in an earlier section of this chapter, but with the benefits come risks and concerns about security, privacy and confidentiality.

Before an EHR implementation can be started there are key issue that need to be in place for such a project to succeed. This study will not only attempt to identify these key success factors but also evaluate them in the South African environment to answer South Africa's readiness to adapt a national EHR.

Overview

This document has been divided into six chapters.

Chapter 1	consist of a general overview, defines the problem statement	
	and delimitations for the study.	
Chapter 2	hosts the literature review with detail on the cost, patient	
	identifiers, medical records with a focus on standards and	
	interoperability and conclude with resistance towards the	
	electronic health record.	
Chapter 3	discuss the study methodology with detail about the proposed	
	quantitative case study method selected for this study.	
Chapter 4	analyses the results obtained through the case study analysis	
Chapter 5	review the results and discuss the South African case.	
Chapter 6	concludes the study	

Chapter 2

Literature review

Introduction

The number of national electronic health record initiatives around the world is growing rapidly. Canada Health Infoway CHI (2009) recorded at least 23 countries where national electronic health record strategies are in place for the entire country and these strategies have been or are being implemented.

National electronic health record initiatives have clearly moved beyond North America, Europe and Australasia to now include Eastern Asia, the Middle East and Central America. Further, there are a number of additional countries who are on the cusp of commencing new national electronic health record initiatives.

Looking closely at these countries it is interesting to note that:

- they all had their own unique starting points;
- each are using a variety of deployment approaches;
- each is following its own path to deploying the electronic health record;
- each is moving at its own pace; yet all are striving to achieve the same end,
 better patient care. (CHI, 2010)

However, the type and extent of electronic health records vary and what one country calls an EHR may not be the same as that developed in another country, some authors like Gunter and Terry (2005) refer to an Electronic Health Record (EHR) where others like Luo (2006) refer to Electronic Medical Record (EMR). Although work has been undertaken by institutions like Kaiser Permanente on some form of a computerised patient healthcare information system, as yet not many hospitals have successfully introduced an electronic health record with clinical data entry at the point of care.

The World Health Organisation(WHO), (2006) highlight although interest in automating the health record is generally high in both developed and developing countries unfortunately, in some cases, the introduction of an EHR system seems overwhelming and almost out of reach to many healthcare providers and

administrators as well as medical record/health information managers. The obstacles may not be available technology but technical support and the cost of changing to an electronic system coupled with insufficient healthcare funding. In many developing countries costs, available technology, lack of technical expertise and computer skills of staff, and lack of data processing facilities are in fact major issues which would need to be addressed before implementation is possible.

Each project has limitations and barriers that have to be identified and addressed before you start any implementation. This chapter will briefly discuss the review of the benefits and barriers of the EHR but discuss in more detail the most discussed barriers of electronic health record implementation.

What are the benefits of implementing an EHR?

The literature supports that EHRs or as referred to by some authors (Luo 2006), EMRs holds tremendous benefits for the health care industry. The most often cited benefits were listed by authors Cherry, Ford and Peterson (2009) as (a) interoperability; (b) integration among clinical systems; (c) standardized language; (d) decision support; and (e) physician usage.

The EHR101 report published by McKesson made the statement "An EHR is one of the best business and clinical investments that a practice can make", and listed benefits of the EHR in four main benefit categories; (a) cost reduction; (b) revenue enhancement; (c) improved administrative efficiency and (d) improved clinical efficiency, patient care and service.

Other benefits to EHRs include: improved quality and patient safety, reduced lengths of stay (in acute care settings), increased efficiency and timeliness of care, avoidance of adverse events such as medical errors, improved treatment protocols, improved continuity of care, instant availability of charts, rapid and informed response to patients' telephone questions, refill requests, communication and education modules for enhanced patient understanding and satisfaction, accuracy and completeness of notes, and effective disease management by gathering

extensive data quickly and efficiently on patient populations (Health Information Management Systems Society HIMSS, 2003).

Most of the benefits from implementing an EHR are directly or indirectly patient related. Having test results available to the physician will avoid duplicate tests being ordered, while information about allergies and current medication can avoid serious reactions to the patient. An EHR does not just benefit the patients; it will benefit the main users by assisting and improving the duties and routines of physicians and health care institutions.

What are the barriers of implementing an EHR?

The list of possible barriers during the implementation of an EHR can be extensive, although some barriers may be consistent when you compare implementing an EHR at institutional/Institution level and implementing at a national wide level, the impact of the barriers may differ.

The WHO (2006) listed possible barriers as:

- Clinical data entry issues and lack of standard terminology
- Resistance to computer technology and lack of computer literacy
- Resistance by many healthcare professionals
- High cost of computers and computer systems and funding limitations
- Concern by providers as to whether information will be available on request
- Concerns raised by healthcare professionals, patients and the general community about privacy, confidentiality and the quality and accuracy of electronically generated information
- Quality of electronic healthcare information and accuracy of data entries
- Lack of staff with adequate knowledge of disease classification systems
- Manpower issues lack of staff with adequate skills
- Environmental issues electrical wiring and supply of electricity, amount and quality of space needed for computers, etc.
- Involvement of clinicians and hospital administrators

The primary barriers to EHR implementation identified in the literature and summarised by Cherry, Ford and Peterson (2005) are: (a) costs; (b) physician acceptance; (c) disruption of current clinical routine; and (d) lack of documentation standards. Cherry, Ford and Peterson (2005) summarized more specific points from the literature, EHR implementation barriers include:

- Funding and costs for implementation (Anderson, 2004; Ash, Stavri, & Kuperman, 2003; Bates & Gawande, 2003; Boudreau, Davis, Delery, Korbich, Lambert, Vogel, & et al., 2005; Ford, Menachemi, & Phillips, 2006; Hillestad, Bigelow, Bower, Girosi, Meili, Scoville, & et. al, 2005; Miller, Hillman, & Given, 2004; Valdes, Kibbe, Tolleson, Kunik, & Petersen, 2004).
- Lack of interoperability and the excessive number of commercially available EMR systems (i.e., Valdes identified 264 systems in use) (Valdes et al., 2004).
- Lack of standards adoption (Abbott, 2003; Brookstone, 2004; Dougherty, 2005;
 Hillestad et al., 2005; Middleton, Hammond, Brennan, & Cooper, 2005).
- CCHIT is working on establishing standards (Lourde, 2009).
- Increased time for documentation (Miller & Sims, 2004; Poissant, Pereira, Tamblyn, & Kawasumi, 2005).
- Perceptions that EMRs interfere with clinical workflow (Ash & Bates, 2005;
 Chambliss, Rasco, Clark, & Gardner, 2001).
- Physicians who view EHR decision support as "cookbook medicine" (Sprague, 2004).
- Confidentiality, privacy, safety of records, and HIPAA violations (Hillestad et al., 2005; HIMSS Leadership Survey, 2004; Soper, 2002; Valdes et al., 2004; Waegemann, 2002).
- Software issues such as lack of an efficient way to view the overall picture of patient progress and care, lack of automatic prompts, and poor system navigability (Smith et al., 2005).
- Vendor issues including vendor volatility and immaturity of software (Brookstone, 2004; Ford et al., 2006; Podichetty & Penn, 2004).
- Difficult implementation processes (Ash et al., 2003).
- Training concerns (Brookstone, 2004).

The following barriers have been broadly discussed and debated by authors and will be discussed in more detail in the following section.

Cost of implementing an EHR

One of the key consideration factors before starting an implementation is the funding and costs of implementing an electronic health record; the costs involved in adopting an electronic health record could range into billions of dollars. Considerable uncertainty exist regarding the cost associated with EHR initiatives, due to the continuous adjustment of costs associated with evolving technologies and the short life of products in the IT industry.

WHO (2006) suggested perceived high costs of computers and computer systems and lack of funds for healthcare has been seen as a major issue in the development and implementation of an EHR. Health administrators and government officials see such an undertaking as an investment that must be self supporting in a time when available funding for healthcare is limited and overall healthcare costs are escalating. The initial outlay associated with the introduction of an EHR would undoubtedly be significant, both in time and finance, to tailor it to the individual needs of the institution/ country and to deal with the broader aspects of the change to the new system. It is therefore important to identify specific requirements, as well as clinical practice guidelines. In addition, administrators should undertake a comparison of current system costs plus perceived costs for the new system against the proposed benefits for the change to determine the long-term value of the anticipated EHR system.

Implementation costs for a given installation will vary considerably, depending on what is being implemented and what systems, if any are already in place. Some Implementation projects are able to negotiate very favourable agreements with vendors who already provide services to a large area or speciality (such as laboratory services). Essentially, the vendors add the EHR capabilities at a favourable rate in order to smooth integration and build customer commitment. But other installations can be extremely expensive, for example, the roll out of an EMR across the entire Kaiser Permanente network was reported to cost more than \$1 billion. Kaiser Permanente is one of the US's largest not-for-profit health plans,

serving more than 8.6 million members, with 35 hospitals and 15,129 Physicians of various specialities. (National Institute of Health National Centre for Research resources NIHNCRR, 2006)

The organization of a country's health care system and health care financing can have a significant impact on health IT adoption. In Denmark, Finland, and Sweden, and other countries with single-payer health care systems, the costs and benefits of investing in health IT systems are better aligned than they are in countries such as the United States, where multiple governmental and nongovernmental entities pay for health care. Moreover, in these nations governments can afford to take a longer term view and make investments that might not pay off fully in the short term. More government involvement in health care also leads to more accountability. One of the reasons that Finland and Denmark have achieved significantly higher rates of EHR adoption in hospitals than other countries is that their hospital systems are government-run. Thus, political leaders have direct accountability for the quality of the care delivered at these institutions, and the government can prioritize needed upgrades and recoup public investment in hospital IT systems. Sweden's health care system is decentralized but emphasizes universal access to quality health care and is primarily supported by public financing. (The International Technology & Innovation Foundation, 2009)

NIHNCRR (2006) offered an American Hospital Association survey done in 2006 found that "the median annual capital investment on IT was over \$700,000 and represented 15 percent of all capital expenses. Operating expenses were much higher—\$1.7 million, or 2 percent of all operating expenses. Those with more advanced systems—and especially advanced CPOE (Computerised Physician Order Entry) systems—spend even more."

On the contrary a project initiated by the Office of the National Coordinator for Health Information (ONC), surveyors found that hospital administrators and physicians who had adopted EHR noted that any gains in efficiency were offset by reduced productivity as the technology was implemented, as well as the need to increase information technology staff to maintain the system. (The International Technology & Innovation Foundation, 2009)

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According to Gunter and Terry (2005) the medical community is concerned about costly dependence on propriety technology companies, which could potentially monopolize the hardware and software required for interoperability. One possible solution would be for the mechanism of implementation of the EHR to be a public service built to public standards and/or under patient control. Even though the use of the EHR could generate cost savings for the health system at large that might offset the EHR's cost, many physicians might not be able to reduce their office expenses or increase their revenue sufficiently to sustain the system. The use of the EHR could for example reduce the number of duplicated diagnostic tests, but that benefit does not increase the revenue of the Physician.

In addition many Physicians who run smaller practices are concerned about the cost to the providers in terms of hardware and software initial costs and a further maintenance, versus the value they will derive from adoption in the form of return on investment.

NIHNCRR (2006) claim measuring return on investment (ROI) of IT systems to be difficult for any industry. Most research has been focused on how to compute ROI for medical IT systems such as EHRs, but do not present the results of such studies. The qualitative benefits of EHRs are generally accepted and have been presented anecdotally throughout the literature.

These include, but are certainly not limited to:

- Improved quality and patient care.
- More efficient tracking of patients and costs.
- Benefits to the business of healthcare.
- Better documentation and improved audit capabilities.
- Avoidance of repeating expensive tests and more time spent with patients

Walker (2005) and her colleagues argue that interoperable health information infostructure could produce cost savings in excess of \$77 billion per year—an amount far in excess of the estimated costs of implementation over time. Creating that system, though, will involve a long series of onetime, indirect costs. Although the projected cost savings are compelling in the final state, successful implementation

will depend upon a series of successful transition states, where the business case may not be as clear. In many instances, those who must bear the costs will not be those who will harvest the savings. Implementation will require carefully coordinated national policy and organizational planning.

Literature agrees that although the cost of implementing an electronic health record, either at institutional or national level, is extensive, the return on investment when measured in time, money and clinical benefit does justify the investment. The implementation cost of an EHR may not consider the maintenance phase after the initial implementation. I believe an EHR at national level will never be self-sufficient and will always require funding for maintenance, and this had to be included in the initial budget plan.

Patient Identifier

It is a key issue in health information management as it is vital that each patient is uniquely identified, this is not just essential for an automated systems but for manual record keeping as well. If a national identification number exist it is the preferred method of patient identification. In countries where a national identification number does not exist, another piece of information needs to be used.

Some countries use:

- Biometric characteristics fingerprint scanning has been a preferred choice of identification. Added benefit of this type of identification is that it will be effective even if the patient is non-responsive on arrival at any institution.
- The patient's mother's maiden name this has proven to be useful because it does not change but some patients do not know their mother's maiden name.
- Father's first name again some patients don't know their father's first name
 (WHO, 2006)

This unique patient identifier is according to NIHNCRR (2006) the core of an EHR and links all clinical observations, tests, procedures, complaints, evaluations, and diagnoses to the patient. The identifier is sometimes referred to as the medical record number or master patient index (MPI). Advances in automated information

systems have made it possible for organizations or institutions to use MPIs enterprise wide, called enterprise-wide master patient indices.

There are several key issues in making an effective Electronic Medical Record, EMR. One of the primary problems is the unique patient identifier or master patient index. It is common in the emergency setting for patients to arrive unconscious, and therefore they may be assigned a medical record number that is later determined to be unnecessary when the patient is able to provide identifying information. (Luo, 2006) Emergency cases are always a concern when identifying a patient is concerned. In such cases a unique identifier, unless biometric characteristics is use, may not be available at initial admission but a correction can be done once the patient is identified to ensure the correct record is updated.

In a recent study Kotze (2008) explored the possibility of using a linkage model for patient identification in an attempt to establish a longitudinal patient record. Probabilistic and deterministic methods were explored and tested on South African names and surnames. Contrarily to what was anticipated, no probabilistic matching problems were experienced when using African surnames and first names. Both Soundex and String comparison algorithms were used in the probabilistic matching and the results were good and useful.

The following observations were made by Kotze (2008) regarding the patient master index in the data models used in this study to strengthen the rationale of using probabilistic record linkage methods:

- Lack of a unique identifier such as the South African Identification Number.
- Different spellings of a SURNAME, FIRSTNAME for the same patient.
- Different combination of INITIALS for the same patient.
- Missing values in GENDER and BIRTHDATE, or BIRTHDATE that will differ because of the longitudinal nature of records.

One of the important contributions the study (Kotze, 2008) made was stated as "A novel and real-world tested algorithm was developed to construct a longitudinal patient record (LPR) from the integrated mapping table. The algorithm in turn

provided the foundation for the LPR of an Antiretroviral Therapy ART patient. The ARV LPR is a first for South Africa and for that matter, the whole Africa.

No Literature attempted to prove that one method of patient identification is better than the next, but all agree that the need for unique patient identification is essential for a successful EHR. Multiple sources used the example of two patients having the same name and surname, this is a very real issue in some countries, so in my opinion Name and Surname is not an advisable method of patient identification.

Medical Records

The focus of medical records has evolved over time, most health care institutions have a patient record that is a paper based file per patient and these files are stored at institutional level. Despite improvements in the medical record, paper-based systems have many limitations. In large hospitals, these records may be unavailable because they are stored in the clinic or business office when the patient comes into the emergency room. Access to records is limited to one person at a time, and such access must be on site.

Even in a solo practice, paper records may require a large area for storage, and must be organized for ready access. Luo (2006) claim legibility to be a major issue of paper-based records. For example, researchers in a Spanish hospital found 15% of 117 records were illegible. Paper is not a durable media, and is susceptible to both water and fire. Records are often lost or missing, and backup of paper-based records is unwieldy, requiring time and resource-intensive effort. Security of records is limited to locked storage, without the ability to log record access.

In some instances there is a tendency to expect that with the introduction of an electronic health record many of the problems currently experienced in maintaining paper health records will be eliminated. This is not the case. An electronic health record is not a simple replacement of the paper record.

Although the introduction of a fully electronic health record system may seem far off in many healthcare institutions/countries they are being introduced rapidly in others and there is no doubt that the future of health information management lies with automation and the automatic transmission of information required for patient management at all levels of healthcare. (WHO, 2006)

Patients visit multiple providers during their medical encounters, for example an outpatient visits the doctor, who sends him for an x-ray and finally refer him to the Physiotherapist after diagnosis. Each of these individual providers can have their own medical records with their own numbering system. If the same patient was admitted to hospital, the admitting institution would have another medical record for the patient.

Each of the providers includes different information in their records and has their own standards. The quality of medical records may also vary from one institution to the next. In order to move an electronic heath record the various institutions would need to be audited to ensure that the manual records are complete and sufficiently documented.

WHO (2006) highlighted if identified problems are not addressed and remedied prior to introducing an EHR system merely automating health record content and procedures may perpetuate deficiencies and not meet the EHR goals of the institution/ country. Current problems identified in healthcare documentation, as well as privacy and confidentiality issues must be addressed and quality control measures introduced before a successful change can be implemented.

WHO (2006) wrote:

Centralised numbering systems for medical records, where the patient have a unique Medical Record number and individual encounter numbers for each visit, is essential to manage a medical record. Due to misspelling of names and other human factors any institution would always have a problem with duplicate records, this highlight the need for a unique patient identifier for medical records.

Each institution must have a Master Patient Index (MPI); it is an index that includes all the patients that have visited the institution. The MPI should contain identifying and demographic information to be able to identify a patient's medical record. This index would include the patient's full name, institution unique number, and address, date of birth, age and national identification number.

Luo (2006) pointed out that an EHR is more than an electronic version of the paper-based record. It is a computer-based system for managing and delivering data required for patient care. The EHR is more than a database because it offers many functions, such as an integrated view of patient data, clinical decision support, clinician order entry, integrated communications support, and access to knowledge resources. The EHR should interface to other systems, such as billing, pharmacy, radiology, scheduling, and practice management.

According to the Medical Records Institute (Luo, 2006), five levels of an Electronic Healthcare Record can be distinguished (Table).

• Level 1:	The automated medical record is a paper-based record with some
	computer-generated documents.
Level 2:	The computerized medical record makes the documents of level 1
	electronically available
• Level 3:	The EHR restructures and optimizes the documents of the previous
	levels, ensuring inter-operability of all documentation systems.
• Level 4:	The electronic patient record (EPR) is patient-centred record with
	information from multiple institutions.
• Level 5:	The electronic health record adds general health-related
	information to the EPR that is not necessarily related to a disease

These levels are helpful in determining what type of EHR is necessary for different practice settings. Solo practitioners may only need a level one record system, but for integration with a local hospital for continuity of information transfer, a more sophisticated system is needed.

Resistance by some medical practitioners and health professionals generally to a change from manual to electronic documentation may be a problem in both developed and developing countries, this is discussed in more detail in a separate section. Most health administrators and information managers are aware that it may take time to change or at least modify health practitioner behaviour and attitudes. The reason for wanting to change to an electronic system is important. WHO (2006) acknowledge that many persons involved in healthcare today expect to move from a

paper to a paperless environment. This is a major step and has only been successfully achieved in a few healthcare institutions to date. Institutions should not focus on just going paperless.

They should focus on encouraging departments and healthcare practitioners to move to an electronic system to:

- Improve the accuracy and quality of data recorded in a health record.
- Enhance healthcare practitioners' access to a patient's healthcare information enabling it to be shared by all for the present and continuing care of that patient.
- Improve the quality of care as a result of having health information immediately available at all times for patient care.
- Improve the efficiency of the health record service.
- Contain healthcare costs (WHO, 2006)

Governing bodies will use their statutory power to develop rules and guidelines to manage the quality of clinical and administrative data but the quality of the data will not only depend on the institutions but on the individual users.

Standards

A "standard" according to NIHNCRR (2006) is "established by consensus and approved by a recognized body that provides rules, guidelines, or characteristics for activities." Standards are created for many technical and clinical domains, as described below. EHRs use both technical and clinical standards.

eHealthnews (2010) reported an international EHR standard ISO/CEN EN13606 was published in a five part standard, whose final part was published jointly by ISO and CEN in February 2010. This standard will define the way that clinical information should be represented so that part or all of a patient's health record can be transferred between systems within or between countries in a way that faithfully preserves its meaning and its confidentiality. The EN13606 standard has been strongly supported by many countries during its development and balloting in CEN (in Europe) and ISO (Internationally), and is now starting to feature in large-scale

eHealth programme architectures in countries such as Sweden, United Kingdom, Slovakia and Brazil.

EHR vendors have been implementing some standards, but have had a great deal of variation in their implementation methods, which results in systems that cannot interoperate. WHO (2006) stated 'Electronic patient records today are highly idiosyncratic, vendor- specific realizations of patient record subsets. They adopt few, if any, health information standards, and very rarely accommodate controlled terminologies where they might be sensible. The reason for this epidemic of incompatible data has more to do with the limitations of available information standards and machineable vocabularies than with any fundamental unwillingness to adopt standards. A compelling business case, for system vendors or patient providers, simply has not emerged to foster standards adoption and systems integration.'

NIHCRR (2006) argued that the use of standard clinical vocabularies and structured data organization greatly enhances the ability of clinical systems to interoperate.

To create interoperable EHRs, standards are needed for:

- · Clinical vocabularies.
- Interoperability messages Healthcare message exchanges, in which one system exchanges messages with another.

Clinical Vocabularies

Vocabularies play a strategic role in providing access to computerized health information because clinicians use a variety of terms for the same concept. For example, either "leukopenia" or "low white count" might be written in a patient record—usually these are synonyms. Without a structured vocabulary, an automated system will not recognize these terms as being equivalent.

Standard vocabularies are a means of encoding data for exchange, comparison, or aggregation among systems.

When a clinician evaluates a patient, the documentation usually captures free text or unstructured information, such as history and physical findings. As the clinician evaluation process continues, the unstructured data is transformed (often by a clinical coding specialist) into more structured data that is often linked to payment processing and reimbursement. These claims-related structured data sets (which are different from clinical vocabularies) include Current Procedure Terminology (CPT) codes, International Classification of Diseases (ICD), and Diagnosis Related Groups (DRG). Implementing standardized clinical vocabularies and disease ontologies into clinical data capture systems can alleviate terminology inconsistencies when data is captured at the point of care. Logical Observation Identifiers, Names and Codes (LOINC) for ordering lab tests and Systematized Nomenclature of Medicine—Clinical Terms (SNOMED-CT) for recording test results, along with many other existing vocabularies, provide well-defined meanings for specific terms that can be standardized across applications. These vocabularies lend themselves to much more detailed and relevant clinical analyses, especially when measuring outcomes for clinical research support, but only when they are implemented in a uniform way. (National Institute of Health National Centre for Research resources, 2006)

The ICD-CM (Clinical Modification) was developed by the National Centre for Health Statistics for use in the United States to ensure accurate classification of diseases treated and procedures performed. The use of this standard coding helps to establish an international standard terminology but you need trained staff to complete the correct coding on the medical records. (National Institute of Health National Centre for Research resources, 2006)

Coded terminologies, such as the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) and International Classification of Diseases are also crucial to EHR systems in structuring data for interchange and storage. Similarly, the Current Procedural Terminology codes provide a coding scheme for diagnostic and therapeutic procedures. The Systematized Nomenclature of Medicine is another comprehensive coding system originally developed by the College of American Pathologists. Logical Observations, Identifiers, Names, and Codes (LOINC) is a naming system for laboratory tests and observations, such as vital signs and electrocardiogram. These are just a handful of the many coding schemes used in EHR systems. (Luo, 2006)

Interoperability Messages

Hospitals and other organizations of Health care use different computer software product that was chosen by their management to serve the individual needs of the operations. To establish an EHR all these various systems need to "communicate" (called interface) with each other, to send information from one system to another. (World Health Organization, 2006)

Health Level Seven International (HL7) is the global authority on standards for interoperability of health information technology with members in over 55 countries. HL7 specifies a number of flexible standards, guidelines, and methodologies by which various healthcare systems can communicate with each other. Such guidelines or data standards are a set of rules that allow information to be shared and processed in a uniform and consistent manner.

HL7 develops Conceptual Standards (e.g., HL7 RIM), Document Standards (e.g., HL7 CDA), Application Standards (e.g., HL7 CCOW), and Messaging Standards (e.g., HL7 v2.x and v3.0). Messaging standards are particularly important because they define how information is packaged and communicated from one party to another. Such standards set the language, structure and data types required for seamless integration from one system to another. (James, 2005)

Standards are a vital element of EHR systems in terms of interoperability and communication. Health Level 7 is a standards developing organization accredited by the American National Standards Institute (ANSI). It produces a standard for hospital information systems communication used at most institutions for the exchange, integration, sharing, and retrieval of electronic health information. ANSI X12, or Electronic Data Interchange, is the computer-to-computer exchange of structured information typically used for billing systems. Digital Imaging and Communications in Medicine (DICOM) is a comprehensive set of standards for handling, storing and transmitting information in medical imaging.

Schloeffel,P et al discussed the relationship between CEN 13606, HL7, and *open*EHR. The development and adoption of national and international standards for EHR interoperability is essential for:

- Sharing patient health information between health professionals in a multidisciplinary shared care environment.
- Interoperability between institutions within an enterprise, a regional or national health system, or in future, across national borders.
- Supporting interoperability between software from different vendors.

Standardisation is essential for the clinical data transfer between health systems to achieve an EHR. But the standardisation does not define what information will be transferred that will still have to be defined by the regulating bodies

Privacy and confidentiality

Barber discusses changes in the delivery of healthcare and how individuals need to be protected by protecting their electronic health records. Security issues and data protection need to be taken seriously and health information professionals need a code of ethics to ensure security is maintained.

Security measures as stated by WHO (2006) for users of the EHR should include:

- Audit trails are essential to monitor the user's activity on the EHR system and what information was accessed.
- If information is added or edited on the system the information need to be verified by the authorised user.
- Access control for users, with different levels of access as to what the user is authorised to see and do on the EHR system.

 Network security measures on both the administrator of the EHR system and the users need to be in place.

The EHR Manual (WHO, 2006) recommend that a Steering Committee appoint a team to develop and maintain a medico-legal checklist, incorporating government regulations, to guide the implementation and on-going use of the EHR. Remember that measures need to be directed at ensuring appropriate security and storage of information to prevent improper disclosure.

Within the institution/country an Information Security Policy should be in place, with standards, implementation guidelines, and an action plan. Compliance with such a policy will safeguard the accuracy and completeness of information and ensure that:

- Only authorized persons have access to healthcare information.
- Dependant privacy policy and related legislation are upheld.
- Information is stored and handled in a secure manner Implementation of an Information Security Policy will ensure that information related to health encounters will be protected from unauthorized access when the EHR is operational. It is important to remember that for a manual health record system the privacy and confidentiality of patient information in an electronic health record must be protected at all times. (National Institute of Health National Centre for Research resources, 2006)

Gritzalis (2004) stressed the need to raise awareness and provide guidance to online data protection is discussed together with the equally important issue of applying privacy-related legislation in a coherent and coordinated way. The issue of patient profiles that reveal sensitive information is highlighted and focuses on countermeasures that can be employed to protect the privacy of personal and medical data transmitted during electronic medical transactions.

Resistance

Resistance to Computer Technology and Lack of Computer Literacy

Even in today's environment many healthcare professionals still resist the use of computer technology when attending to a patient. They prefer to write by hand, finding it difficult or uncomfortable using electronic media. Newer technology, however, such as small wireless devices, notebook computers, and mobile phones with data capture capability, as well as improvements in voice and handwriting recognition devices are beginning to address such issues. In many cases, however, the issue is not resistance to computer technology as such but a lack of computer literacy.

This can be a major issue, not only for medical and nursing staff but also for clerical and other staff. If automation is planned, attention needs to be paid to this issue. Some institutions have found that the introduction of a basic computer skills course for personnel has helped alleviate the situation. Resistance to attending such courses could be a problem and the staffs needs to be encouraged and supported to overcome their reluctance. Successful implementation of an EHR will be dependent on the computer skills of all healthcare professionals and other staff. Although in today's world many use computers, particularly the Internet, some are still not proficient in this area as they do not routinely use computers at work or at home. (WHO, 2006)

Strong Resistance to Change by Many Healthcare Providers

Overcoming uncertainty and resistance to change will also challenge the implementation team. As with resistance to computer technology this has been one of the most discussed issues affecting the introduction of electronic healthcare systems over recent years and one that needs to be addressed before proceeding to EHR implementation. For many health professionals the change to entering patients' health record data via a computer or other electronic device may be daunting. This issue will require intensive training of healthcare practitioners to help them become more comfortable with, and ensure acceptance of, the new

technology. Overcoming resistance to change by healthcare professionals, whether in a manual system or an electronic one could be a challenge but with the right strategy could be overcome. As mentioned previously, the main strategy to have in place to help overcome such resistance is to have them involved from the outset in discussions on the development and implementation of an EHR. As well as being trained in the technology, they need to be involved in system selection and design. (WHO, 2006)

Physicians strongly resist health IT that they view as controlling their behaviour. Efforts to modify decision-support systems by presenting options for providers, rather than just warnings, show promise in this regard.(Aarts and Koppel, 2009)

Summary

An EHR implementation initiative is first and foremost controlled by the allocated funding, an implementation as with any new product or process require resources. In an EHR implementation the main resources required can be divided into financial and then technical; the technical resources are indirectly financial as the skill and hardware required do not come cheap. The cost of an EHR implementation is extensive and will be influenced by the size of the institution/country as well as existing systems but in most cases lack of anything existing.

In order to use an EHR efficiently you need to identify a patient correctly and avoid duplicate names and surnames being the cause of medical errors due to identifying the patient incorrectly. National identification numbers are the ideal to use for as the unique patient identifier. There will always be restrictions with any method of patient identification but the institutions/country need to choose the method best suited for them.

Existing medical record systems must be reviewed and the paper-based problems need to be addressed before attempting to move to any electronic automation. The implementation process is normally a good way to clean up shop and start with a clean slate. Resistance to change to an EHR will be found to not only be from the physicians but also from hospital administration staff, with the main reason being

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computer illiteracy. It is essential to train all the users to be able to change their manual process to electronic.

During an EHR implementation on either institutional or country level there may be a need to communicate with other existing clinical systems. Standardisation of both clinical vocabularies and interoperable communication methods, have been a continuous improving process that delivered globally acceptable standards like the HL7 standards and ICD coding.

Patients need to feel that their profile of clinical information will only be seen by the right people. Security policies need to be in place to ensure that the privacy and confidentiality of patient data is controlled through audit trails and access control.

CPOE systems can play a significant role in the EHR but are not a required component. The use of CPOE can ease the ordering of tests and medications through automation. Benefits will not only be financial, due to control on tests and medications that can be ordered, but mainly patient safety through decision support warning about allergies etc.

The following chapter discusses the research paradigm used in the study to answer the research question stated in chapter 1.

Chapter 3

Methodology

Introduction

This research study will use a qualitative case study research method approach, to analyse the data and debate an opinion to answer if South Africa is ready for a National Electronic Health record. This chapter will discuss why this approach was chosen.

Research paradigm

The type of research question is the most significant in determining the most appropriate approach. Figure 1 based on Yin (1994), summarises the different kinds of research questions and methods that are most appropriate. Who, what and where questions can be investigated through documents, archival analysis, surveys and interviews. Case studies are one approach that support deeper and more detailed investigation of the type that is normally to answer how and why questions.

Figure 1: Choosing a Research Strategy		
Strategy	Form of research questions	
Experiment	How, Why	
Surveys	Who, what, where, how many, how much	
Archival analysis	Who, what, where, how many, how much	
History	How , why	
Case study	How, why	

(Rowley, 2002)

Mack et al (2005) justified the strength of qualitative research is its ability to provide complex textual descriptions of how people experience a given research issue. It

provides information about the "human" side of an issue – that is, the often contradictory behaviours, beliefs, opinions, emotions, and relationships of individuals. Qualitative methods are also effective in identifying intangible factors, such as social norms, socioeconomic status, gender roles, ethnicity, and religion, whose role in the research.

As part of the decision on which approach to use you need to look at the comparison between qualitative and quantitative approaches as set out in Figure 2. The Table uses four areas for the comparison being general framework, analytical objectives, question format, data format and flexibility in study design.

Figure 2: Comparison of quantitative and qualitative research approaches

	Quantitative	Qualitative
General framework	Seek to confirm hypotheses about phenomena. Instruments use more rigid style of eliciting and categorizing responses to questions. Use highly structured methods such as questionnaires, surveys, and structured observation.	Seek to explore phenomena. Instruments use more flexible, iterative style of eliciting and Categorizing responses to questions. Use semi-structured methods such as in-depth interviews, focus groups, and participant observation.
Analytical objectives	To quantify variation. To predict causal relationships. To describe characteristics of a Population.	To describe variation. To describe and explain relationships. To describe individual experiences. To describe group norms.
Question format	Closed-ended.	Open-ended.
Data format	Numerical (obtained by assigning numerical values to responses).	Textual (obtained from audiotapes, videotapes, and field notes).
Flexibility in study design	Study design is stable from	Some aspects of the study are

beginning to end.	flexible (for example, the addition, exclusion, or wording of particular interview questions).
Participant responses do not influence or determine how and which questions researchers ask next.	Participant responses affect how and which questions researchers ask next.
Study design is subject to statistical assumptions and conditions.	Study design is iterative, that is, data collection and research questions are adjusted according to what is learned.

(Mack et al, 2005)

The major assumption of qualitative research is that there are many ways of seeing the same thing especially when humans and cultures are concerned and that the researchers' observations of the world are crucial to the ultimate outcome of the research. That is in opposition to the major assumption of quantitative research, which assumes that truth can only be found in numbers and statistics away from the biases of individuals. (Leedy & Omrod, 2005)

A case study can be defined as a type of qualitative research in which in-dept data are gathered relative to a single individual, program or event, for the purpose of learning more about an unknown or poorly understood situation. (Leedy and Ormrod, 2005) This study will use a case study to gather data to define the key success factors when implementing an EHR. Implementation of EHRs at national level is not only unknown to some people but is poorly understood by others.

Case studies have often been viewed as a useful tool for the preliminary, exploratory stage of a research project. (Rowley, 2002) The scope for this study only include the key success factors for the implementation of an EHR, but this study can form the basis for future research projects that can widen the scope of this subject.

Critics of the case study method believe that the study of a small number of cases can offer no grounds for establishing reliability or generality of findings. Others feel that the intense exposure to study of the cases biases the findings. Some dismiss case study research as useful only as an exploratory tool. Yet researchers continue to use case study research method with success in careful planned and crafted studies of real-life situations, issues, and problems. (Soy, 2006)

During the design phase of the case study research, the researcher determines what approaches to use in selecting single or multiple real-life cases to examine in dept and which instruments and a data gathering approaches to use. (Soy, 2006)

This study will use multiple cases. When using multiple cases, each case is treated as a single case. Each case conclusion can then be used as information contribution to the whole study, but each case remains a single case. The researcher must determine whether to study cases which are unique in some way or cases which are considered typical and may also select cases to represent a variety of geographic regions, a variety of size parameters, or other parameters. (Rowley, 2002)

The qualitative case study method was selected to use the selected case studies, to investigate and analyse the various countries that have implemented or are currently undergoing an implementation of an EHR. The research question is open-ended and allows the author an open scope for research parameters. The study design can be adjusted accordingly to what has been learned.

The selection criteria for cases to be used in this study are:

- Use country cases only
- Countries with a population per square km (Use Population divided by Country Area in Square Km) of greater than 2.5
- Country is divided into smaller governing sections; States, Provinces, Territories,
 Municipalities and Regions.
- A Number of Organizations within these countries have implemented some EHR initiative.
- Countries that have undergone Health reform are preferred.

A multiple qualitative study where full literature case studies of countries that implemented or are considering and/or planning to implement electronic health record (EHR) systems will be reviewed.

This study will focus on the following 8 countries:

- Australia
- Belize
- Canada
- Denmark
- Estonia
- Hong Kong
- Netherlands
- Sweden

Cases were firstly screened against the selection criteria mentioned earlier in the chapter. Additional factors had an influence on the chosen cases including language barriers; many countries have their information in their native language.

No EHR projects have been reported as failures, the project may have set out to achieve one EHR model but due to factors unknown to us, the inclusion criteria of the EHR was changed to implement a different model. As mentioned in the previous chapters what one institution or country see as an EHR may be different from the next one.

To achieve the sub-problems of the research question i.e. the evaluation against the South African environment we needed to keep the country selection facts as close to the South African environment as possible.

Data collection and Methods

Leedy (2005) highlights the fact that data is not absolute reality but more manifestations of that reality. Research seeks, through data to discover underlying truths. Data is also transient and ever changing, research can be based on new data that may be outdated by publish date.

Soy (2006) claim that a key strength of the case study method involves using multiple sources and techniques in the data gathering process. The researcher determines in advance what evidence to gather and what analysis techniques to use

with the data to answer the research questions. Data gathered is normally largely qualitative, but it may also be quantitative. Tools to collect data can include surveys, interviews, documentation review, observation, and even the collection of physical artefacts.

This research study will collect extensive primary data about the various country case studies.

The data include documents sources:

- eHealth Strategies from the various countries
- Official internet Government website information
- Official Government publications
- Official statistics
- Internet News articles and reports
- Project and product briefs (where outsourced)
- Case studies from the European Union
- Data available from the World Health Organisation;

Data analysis and techniques

Yin (2003) notes that one important practice during the analysis phase of any case study is the return to the propositions; there are several reasons for this. First, this practice leads to a focused analysis when the temptation is to analyze data that are outside the scope of the research questions. Second, exploring rival propositions is an attempt to provide an alternate explanation of a phenomenon. Third, by engaging in this iterative process the confidence in the findings is increased as the number of propositions and rival propositions are addressed and accepted or rejected.

Data analysis in a case study typically involves the following steps;

- 1. Details about the case this will involve the collection of data about the country cases.
- 2. Categorisation of data the data will be sorted into sub-categories; Unique patient identifier, Standards, Privacy and Security, eCards and stakeholder buy-

- in. These sub-categories were identified in the literature review as key success factors.
- 3. Identification of patterns or possible repetitive behaviour
- 4. Assumption and Generalisations based on cases, for a possible winning formula.

Summary

The approach best suited for this study is a qualitative case study research method. Case studies as a research methods or strategy according to Rowley has traditionally been viewed as lacking rigour and objectivity when compared with other social research methods according, but are widely used because they may offer insights that might not be achieved with other approaches.

Selection criteria based on size and segmentation of the health care and provinces, have been used to select the cases that will be analysed in next chapter. Chapter 4 will discuss the results from the data collections and analysis.

Chapter 4 Results

Introduction

Analysis of the following country case studies; Australia, Belize, Canada, Denmark, Estonia, Hong Kong, Netherlands and Sweden were tabled under the sub-categories to compare the different country parameters with one another.

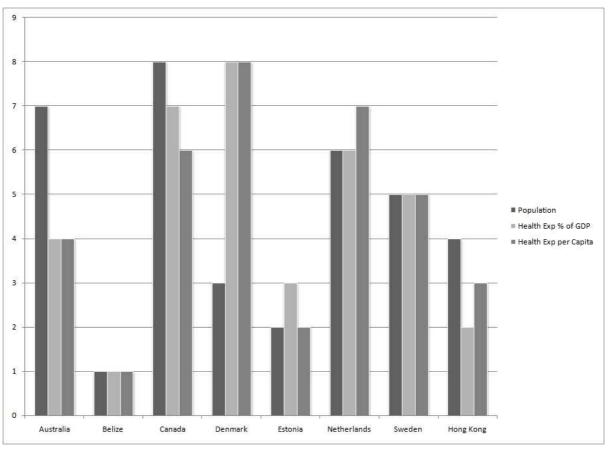
Country facts are listed in the table below, with the cases listed in alphabetical order.

Country	Population (Jul 2011 Est)	Area sq km	Health expenditure, total (% of GDP)	Health expenditure per capita (current US\$)
Australia	21,766,711	7,741,220	8.5	3867
Belize	321,115	22,966	4.9	217
Canada	34,030,589	9,984,670	10.9	4380
Denmark	5,529,888	43,094	11.2	6273
Estonia	1,282,963	45,228	7	1004
Hong Kong	7,122,508	1,104	5.0	1403
Netherlands	16,847,007	41,543	10.8	5164
Sweden	9,088,728	450,295	9.9	4252

The values from the table where plotted on a graph to display a comparison of the country's population and health expenditure (both as a % of the GDPO and per capita) against each other.

The values of population, Health expenditure total (% of GDP) and Health expenditure per capita (current US\$) has been ranked out of 8, with 1 being the lowest and 8 being the highest. Graph 1 is the plotted ranked values per country.

Of the case countries only two countries –Belize (1) and Sweden (5) ranked level on all three variables – a) Population, b) Health Expenditure (% of GDP) and C) Health expenditure per capita.



Australia has the second highest population but ranked at a mere 4th in Health expenditure on both % of GDP and per capita. On the flip of the coin Denmark has a 3rd ranked population but have the highest Health expenditure on both % of GDP and per capita.

The reason for such a difference between these two countries can be contributed to Denmark being a publicly funded health system and Australia a combination of Public and Private funding.

The countries listed above have been analysed based on their implementation of the EHR and the results are categorised in the table below under the headings: Overview, Funding, Unique Patient Identifier, Standards, Privacy and Security, eCards and Stakeholder Buy-in.

Overview Australia Australian, State and Territory Government established the National Electronic Health Records Taskforce in November 1999 to evaluate the potential of electronic health records for the Australian health system. Health Connect, an overarching national change management strategy that establishes and maintains a range of standardised electronic health information products and services for health care providers and consumers was initiated. In 2005, the National E-Health Transition Authority Ltd (NEHTA) was established to develop a national approach to electronic health record for all Australians, the Individual Electronic Health Record (IEHR). The IEHR will include three main components the a) Summary Health profile, this component will include the patient's allergies, medications and diagnoses; b) Event Summaries - including pathology results, radiology reports, referrals and discharge summaries and c) Supported Self Managed Care questionnaires - enabling individuals to contribute to the management of their own care. **Belize** In 2004, the government embarked on health sector reform with support from the Inter-American Development Bank (IDB). Six administrative districts were grouped into four regions and Regional Health Management Teams (RMTs) were created to decentralise planning and decision-making. To support the process, the GoB invested in Electronic Health Records (EHRs). The result is the Belize Health Information System (BHIS), a home grown health IT solution that was installed in 2004 at the Karl Heusner Memorial Hospital (KHMH), the main referral hospital in the country. The BHIS has grown in terms of functionality and geographical coverage. Nationwide roll-out of the BHIS has begun in phases starting with urban areas. In 2008, the supply chain, HIV/AIDS and laboratory modules were added to the system. As at August 2009, the BHIS was developed at KHMH, al 4 Regional hospitals, and urban health centres and polyclinics. Overall, 54 health facilities run by the MOH are networked. Together, these account for approximately 80% of encounters in public health facilities. The BHIS is also deployed in two private hospitals in Belize City. The goal is to have every Belizean covered in EHRs within 10 years. Canada In 1997, the federal ministry of health established the Advisory Council on Health Infostructure, which in turn created a not-for-profit corporation, Canada Health Infoway

(CHI), to spearhead its strategic and infrastructural initiatives and projects aimed at developing a national health information network. Infoway membership consists of the federal/provincial and territorial deputy ministers of health of Canada's 12 provinces (Quebec has elected not to participate.) Infoway's first priority was to have the major components of an interoperable electronic health record system in place within five to seven years across Canada.

In collaboration with the provinces and territories, Infoway has established investments and technology Blueprints to guide collective efforts in building a pan-Canadian EHR.

Specifications for Canada's EHR solution include a) unique identifier for patients, providers, and locations; b) patient-centric EHR that has common definition across Canada

Denmark

Denmark has a history of e-health strategies ranging back to 1996 when the first strategy was launched. Denmark has successfully developed a healthcare data network, and is now implementing a national health portal and a clinical data repository. Although only financial benefits have been documented thus far, anecdotal evidence suggests that Denmark has also achieved clinical benefits from factors such as improved adherence to care guidelines, faster exchange of test results, fewer duplicate procedures and more time for clinicians to spend with patients.

Denmark has a centralized computer database to which 98% of primary care physicians, all hospital physicians and all pharmacists now have access. Danish residents can gain access to their own records through a secure website. The website alerts the patient by email if a doctor, pharmacist or nurse views their records, and allows patients to make appointments and even email their doctor for advice on illnesses that do not require an office visit.

Estonia

The Estonian Electronic Health Record System (EHR) encompasses the whole country, registers virtually all residents' medical history from birth to death, and is based on state developed IT infrastructure. It was launched on 17th December 2008 and since 1st January 2009 all healthcare providers have been obligated to send an agreed number of standardised medical documents, electronic information notes and electronic medical documents to it.

Authorised user of the EHR can benefit from the following services:

 Health event service enables users to browse and search for health related events of patient treatment history. Health related events are for example diagnosis, visit, prescription, operation, diagnostic image, etc.

- Health status service enables users to fetch information about certain health related parameters of a patient. These parameters are for example blood type, pregnancy, allergy, height, weight, smoking, etc.
- Booking service enables healthcare service providers to publish information about their healthcare services and available resources, so that doctors of other institutions and patients can book for appointments at these providers. Booking service keeps track of referrals and appointments.
- Reporting service provides users with prebuilt reports about patient health status. Here one can find Time Critical Reports that summarise information about patient's health events and health status in a way most useful for emergency treatment.
- Document archive service organises all digital documents that are submitted to the central system. One can fetch a document by ID from a document archive.
- Statistics service reorganises facts from patient health related documents for further statistical processing.
- Demographics service collects and reports general information about patient identity, locations, and relationships. The information is based on the data of the Estonian Population Registry, registration documents from healthcare institutions, and information submitted via Patient's Portal.

Consent service maintains data about patients' will expressed in digital documents. Currently there are trustee access rights, healthcare service options, and health record access rights related consents implemented.

Hong Kong

The proposal to develop a territory-wide patient-oriented eHR sharing system has been put forward as part of the proposals in the Healthcare Reform Consultation Document "Your Health, Your Life" published in March 2008, and received broad support from the community among other service reform proposals. The eHR sharing system provides an essential infrastructure for implementing the Healthcare Reform in the following ways

a. Enable patient-centred healthcare – eHR sharing system allows timely sharing of essential and comprehensive medical information of patients. It provides a vital infrastructure for facilitating a seamless healthcare process under which different healthcare providers provide collaborative care centred around the individuals and their health and well-being, which is a key objective of healthcare reform;

- b. Enhance primary care eHR sharing system builds up lifelong records for individuals contributed to and accessible by different healthcare providers. It provides an essential tool for comprehensive, lifelong and holistic primary care for individuals, helps promote the family doctor concept and continuity of care, and enables patients to take greater ownership and control of their health record, and in turn their health; and
- c. Facilitate hospital primary care interface and public-private partnership eHR sharing system connects hospitals and primary care practitioners, and the public and private healthcare sectors. It facilitates better collaboration and interface between different healthcare providers and between different levels of care, and enables patients to receive public and private services at different times without worrying about the transfer of their medical records.

Netherlands

The primary aim of the Dutch government's IT policy for the health care sector is to improve affordability, access and quality by creating the preconditions for an optimum and safe usage of ICT.

The focus in the Netherlands has been on implementation of an electronic medication record and an electronic general practitioner's summary. One of the latest developments in the Netherlands is the Healthcare Innovation Platform (Zorginnovatieplatform, ZIP) Inspiration for Innovation which includes development of technologies for chronically ill and older people.

Local or regional health records are already in use in the Netherlands, but they are not regulated by any specific legal provisions. The proposal of law currently under discussion in the Dutch senate intends to introduce a system for a countrywide shared

EHR. It will, however, only aim at data processing within the Netherlands.

The Dutch electronic health record - as foreseen in the latest available proposal of law - will consist of a set of applications linked to the national infrastructure 'AORTA'. The AORTA infrastructure will provide a national registration system for identification and authentication on the one hand and a reference indexing system, National Switch Point, on the other hand. However, instead of deploying full EHRs linking data from all healthcare information systems at once, the government opted for a gradual deployment of the national EHR. The Electronic Medication Record and a Patient Summary Record for the Locum GP were chosen as the two first chapters of the EHR.

The "Patient Summary Record for the Locum GP" (WDH – Waarneem Dossier Huisartsen) was developed and approved as proof of concept in 2006. It contains a set of basic information based on the professional summary for GPs and is implicitly considered as the patient summary for the entire healthcare system.

The electronic medication record, the electronic out-of-hours record for GPs and the electronic declaration system (for reimbursement) is connected to the national switch point. The data intersection is the core element of the EHR introduction.

Sweden

In Sweden a National Patient Summary (Den nationella patientöversikten- NPÖ) has been in place since April 2008. It is based on experiences from an earlier national patient summary pilot and includes the fundamental condition of patient consent. The implementation is still ongoing and so far the Örebro County Council and the Örebro municipality have subscribed (May 2009). Six more counties (Blekinge, Jönköping, Kronoberg, Stockholm, Södermanland and Västra Götaland) are introducing NPÖ starting in 2010. The introduction of NPÖ is implemented then in the remaining counties and regions in 2011 – 2012

The patient summary provides individual information on current care contacts, personal information, chronic diseases, medical alert information (e.g. allergies) and current medical examination results. Information about the patient's dispensed drugs is stored by

Apotekens Service in Läkemedelsförteckningen (a patient's list of dispensed drugs).

Access to this information by a healthcare practitioner, via NPÖ or otherwise, requires patient consent. This implies that the summary also contains condition-specific data including chronic diseases and medical alert information. Swedish residents also have direct access to their own medical records through the internet. The Läkemedelsförteckningen database is a database of the dispensed drugs that Apotekens Service is responsible for, previously it was held by Apoteket AB. The purpose of the database is to enable more accurate prescriptions and preparation of care for the patient. The data in the database is saved for 15 months.

Prescribers, pharmacists and patients themselves have access to it. It contains information about the patient's name and social security numbers, dates of collection of medicines, the name of the medicines taken out and the quantity and dosage. Patients must give their full consent before prescribers or pharmacists can access their data. All searches in the pharmaceutical list are logged and data is recorded for the patient.

Funding	
Australia	Funding of \$132 million was assigned to NEHTA to progress three significant infostructure projects in the development of e-health, namely to establish the Individual Healthcare Identifier (IHI), the Healthcare Provider Identifier (HPI) and to establish a national clinical terminology. These three initiatives form the building blocks towards a national approach to an IEHR.
	An investment of \$466.7 million over the next two years will establish a secure system of personally controlled electronic health records. This investment includes funding for the first two years of the individual electronic health record business case developed in consultation with all states and territories and the National Electronic Health Transition Authority (NEHTA).
Belize	The BHIS was financed through loans from the Inter-American Development Bank (IADB) and the Caribbean Development Bank (CDB). The cost of the implementation the BHIS is estimated at US\$ 2,755,770.
	The Government of Belize (GoB) will cover an estimated one fifth of the total cost totalling at US\$513,810, this comprises mainly of salaries, per diems and rentals. In addition the government will cover the incremental costs that may occur during the expanding of the BHIS and national data repository.
Canada	Funding of \$500 million announced for the 2009 – 2010 budgets is in addition to \$400 million in support provided to Canada Health Infoway in the 2007 budget by the Canadian government. This brings the Government of Canada's total commitment to this initiative to \$2.1 billion since 2001.
	<i>Infoway</i> 's vision, the implementation and use of EHR records for all Canadians by 2016, is expected to deliver \$6 to \$7 billion in annual benefits.
	To reach the 2016 goal it will require a one-time investment of approximately \$350 per Canadian; to date, Canada has allocated about \$50 per person to develop EHRs.
Denmark	Based on a common Basic Model for EHR the cost of the implementation of an EHR was estimated at about 1.5 –2.5 billion EURO.

	MedCom is funded 50 percent by the Ministry of Health, 35 percent by the Association of County Councils, with the remainder of the funding coming from municipalities, the Danish Pharmacy Association, and other organizations. MedCom has a staff of approximately 15 and a budget of 3 million Euros per year.	
Estonia	The Ministry of Social Affairs received funding from the European Union (EU) Structural Funds in 2005 for the development of four E-health projects: Electronic Health Records (EHR), Digital Images, Digital Registration and Digital Prescription. Of the total costs of these E-health projects approximately €2.2 million), 75% is funded by the EU and 25% by the Estonian State.	
	In a recent interview with eHealth Week 2011 Madis Tiik, EHR project manager and CEO of the Estonian eHealth, Foundation confirmed that Estonia has implemented a national electronic health record (EHR) in 2009 at a cost equivalent to € 7.50 per citizen, or a collective € 10 million.	
Hong Kong	The Hong Kong territory-wide patient-oriented eHR sharing system provides an essential infrastructure for implementing the healthcare reform. The Legislative Council approved in July 2009 a new commitment of HK\$702 million for implementing the first stage of the eHR Programme straddling five years from 2009-10 to 2013-14.	
	To take forward the complex and multi-faceted eHR Development, the Food and Health Bureau set up the eHealth Record Office (eHR Office) in 2009.	
Netherlands	The investigation in the eHealth stategy and implementation of the national EHR I could not establish an estimated project cost. However the source of finance for the project was provided mainly by the Ministry of Health either directly or indirectly. Another financing source is the private health insurance companies but also had	
	significant investment from: - Regular health insurance companies	
	- Provincial & municipal initiatives.	
	- Small scale private equity investments	
Sweden	Sweden has a decentralised healthcare system and the responsibility for financing health operations rests with the principals, making then jointly responsible for most of the financial costs for work that needs to be done at the national level.	

The 21 county councils and 290 municipal councils are however dependent on taxes and central government grants. Both the financing and the organisation of healthcare services are primarily the responsibility of the county councils

The yearly budget amount is recommended by the SALAR board and decided by each county council individually. The national resources 2007-2009 for eHealth estimated 320 million SEK from which county councils contributes 220 and the State 100. These resources face total costs of IT for all county councils together of 6500 million SEK a year. County councils have also risen their funding by about 25% in the recent years.

Unique Patient Identifiers

Australia

There is currently no single method of accurately and reliably identifying individuals or providers. The practice of identifying individuals by simply using their name, address and date of birth is no longer the safest and most accurate way to handle health information

NEHTA proposed a Unique Healthcare Identification Service. This Service will involve the allocation, issuing and maintenance of unique identifiers for individuals (the IHI) and healthcare providers (the HPI). The proposed IHI and HPI will consist of a random number that complies with International Standards Institution requirements and Australian standards for healthcare identifiers. Each number will be linked to records containing appropriate identification and demographic data, one number for the lifespan of the individual. No clinical information is required or will be held on the record.

Individuals will be allocated an IHI and a corresponding IHI record by the UHI Institution. It is intended that the UHI Institution would create the initial IHI data set using personal information currently held by Medicare Australia. Medicare Australia would be required to undertake appropriate consent and notification processes before the IHI can be created, disclosed and used by the UHI Institution.

The IHI and HPI records will consist of three parts – a summary record, an identification record and a demographic record. The data fields contained in the summary record might include an individual's name, sex and date of birth. The identification record contains all of the data fields that were present for the summary record and also additional data fields required to positively identify a particular individual. For example where two individuals might have the same surname and date of birth – it might be

necessary to use the address field to identify the correct IHI and record.

The demographic record contains all the data fields used for the summary and identification records and all the remaining additional data fields which may not have been essential to accurately identify an individual, but are required to provide safe and high quality healthcare. For individuals this information might include a mobile phone number.

Belize

The BHIS uses the social security (SBB) numbers to generate a unique patient identifier. No Interface is available at persent between the BHIS database and those compile by the units outside of the MOH. The same information, registered by a unit like the Vital statistic unit is duplicated and manually created in the BHIS.

The adoption of unique codes (personal identifiers) by key stakeholders (MOH, NHI, SSB ad MOAG) will allow exchange of information within a secure environment. Such exchange is limited currently because different agencies use different identifiers for the same individual.

Canada

Infoway has made significant strides in putting a strategy in place for deploying the key building blocks to achieve this goal, with client registries. As part of the needs assessment, the Infoway team researched feasibility of a national unique patient identifier and found that each province/territory was assigning multiple identifiers to a single patient, a common identifier scheme was lacking across all levels of jurisdiction, and standards were lacking for matching patient data, pointing to the need for a client registry strategy.

To have an effective nationwide EHR, the jurisdictions must have a trusted source for accurately identifying patients within and across jurisdictions, which can be achieved with an Enterprise Master Patient Index (EMPI), the underlining technology of a client registry.

A client registry is a component of an electronic health record (EHR) system that supports the centralized storage and retrieval of patient identification data, and enterprise client identifiers (ECIDs).

A client registry is an electronic directory of all persons who have received health care services. As an integral part of an Electronic Health Record, client registries support

secure access to accurate and timely information for physicians, nurses and other health practitioners, enabling improved diagnosis, treatment and health outcomes for patients. By supporting the unique identification of patients (even if two patients have the same name and birth date, the system can distinguish them), registries help reduce the risk of errors.

Denmark

Since 1968, every Danish citizen receives at birth a personal identification number called "CPR" (Centrale Personregister). It is a ten-digit code of which the first six digits indicate the date of birth, while the last four digits are a serial number. The last digit (control digit) shows the person's gender by giving women an even number and men an odd number.

The CPR-number is registered in the central National Register. In that register comprehensive information about the citizens is stored, including information about the name, address, birth registration, citizenship, marital states, kinship and relations to the national church. It does however not contain any medical information.

The number is mandatory to all persons born in Denmark and persons with a residence permit receive a personal identification number in connection with their permit. The CPR-number is used for identification of the patient, both by public and private healthcare providers. The number must furthermore also be included in all patient records

Estonia

In Estonia, the Personal Identification Code (PIC) functions as a unique identifier for citizens and residents in eGovernment services, including health. Every Estonian has a PIC number, which is included on the certificates of the eID cards. PIC is provided by the Population Register.

The card, which is valid for 10 years, is used for identification but also as a travel document within the EU. ID cards are used for visual identification of persons, to access different services, for electronic identification and for digital signatures and can be verified against the Population Registry.

Patients can show providers any card that confirms their national identification number, such as a driver's licence. European health insurance cards can be issued to those travelling within the EU.

Hong Kong

The eHR for Hong Kong see any patient as a person seeking healthcare services for examination or treatment from a healthcare practitioner. This can also be one who attends for routine checkup at a healthcare institute, or simply a person who wants to maintain one's health data in the eHR.

Information that is required to accurately and uniquely identify a

Person includes:

- A system generated permanent unique identifier for each individual who joins the eHR.
- Identification data, including identity document number, name, sex, date of birth.
 These data should be recorded according to the information on one's identity document.
- Demographic data, e.g. address, phone number. These data helps to contact
 the person for future healthcare. The demographics could also assist in other
 purposes, e.g. address for disease surveillance, nationality for use of healthcare
 service. These data should also be coded as far as practicable.
- Next of kin information which helps to contact the person / family if required, e.g. in emergency.
- Mother-baby linkage information which assists in building a womb-to-tomb
 electronic health record for a person. The linkage should be established at the
 delivery episode, or at an episode closest to the delivery one if that is not
 feasible.

According to the Registration of Persons Ordinance, all residents of age 11 or above who are living in Hong Kong for longer than 180 days must, within 30 days of reaching the age of 11 or arriving in Hong Kong, register for an HKID.

Despite an HKID existing available an eHR unique identifier will be created for each residents, despite their age.

Netherlands

In the Netherlands, the choice was made not to introduce a separate ID for healthcare purposes. The Citizen Service Number (BSN) has been implemented for patient identification as well as for both healthcare insurers and healthcare providers. The usage of BSN has been obligatory in healthcare since the 1st of June 2009, based on

an according legislation. The citizen service number is managed by the ministry for Internal Affairs.

The messaging in healthcare using this BSN is managed by the CIBG, an implementing body of the Ministry of Health, Welfare and Sport. The identification of patients is done with the BSN, the national citizen number. The BSN-registry for use in the healthcare sector is also managed by CIBG.

Sweden

Sweden has a national citizen ID, a so-called "personnummer", which is used in dealing with public agencies, from healthcare to the tax authorities. This personal identity number exists since 1947 and is registered in the "folkbokföringsregistret" or population register.

The personal identity number is used as patient's electronic healthcare ID as a matter of national routine.

Standards

Australia

There has been strong focus in some sectors in recent years on the development of standards by organisations such as NEHTA, National Prescribing Service (NPS) and National Pathology Accreditation Advisory Council (NPAAC).

In 2005, NEHTA commissioned a review to recommend the most appropriate standards for sharing EHR information in the Australian context. The review recognised the current dominance of HL7 version 2 in Australia, suggested that the emerging European EN 13606 EHR communication standard be considered as a logical structure for sharing EHR information, and narrowed the field of standards for potential future information interchange to HL7 Clinical Document Architecture (CDA) standard or one of several proposed serialisations of EN 13606.

The current Australian portfolio of e-health standards (which are predominantly based on use of HL7 v2 messages for information interchange) do not effectively support many of the requirements now emerging in Australia, particularly formal clinical terminology, structured documents and services-oriented architectures. Meeting the requirements will involve the adoption of new standards and the replacement and update of some existing

standards.

This work has resulted in the selection of SNOMED/CT as the standard for clinical terminologies, the development of a national medicines terminology standard and the development of consistent data structures for pathology orders and results. Accordingly all IEHR repositories must be based on consistent national data standards and fully comply with data protection legislative requirements.

Belize

The Ministry of Health (MOH Licensing and Accreditation Standards for Hospitals and In-patient Health Facilities was approved in July 2009;

The quality of standards outlined in this manual is designed to focus on the entire hospital. The first set of standards focuses on those functions involved in diagnosing, treating and educating patients. The second set of standards focuses on functions involved in the overall effective and efficient management of the health care facility. The third set of standards focuses on the technical and support service areas of the hospital. The fourth set of standards focus on safety and responsiveness of the facility to external and internal situations that threaten the normalcy of the operations. The fifth set of standards focus on the functional and physical structure of the facility and the final set of standards is considered non-compulsory since its absence is not intended to affect the efficient operations.

No reference to international standard could be found.

Canada

Different national organizations and provincial standards bodies, that are taking active roles in the definition, development, implementation and evolution of healthcare informatics standards for Canada can use the EHRS Blueprint as a foundation for their discussions, analyses, and decisions.

All exchange of information is done using standards-based interfaces defined in EHR Interoperability Profiles. These profiles are made up of messages using standard message definitions, such as DICOM and HL7. Those messages are further supported by data standards, including reference terminologies such as SNOMED CT and classification systems such as ICD10-CA. These interfaces carry the patient's data between the EHR infostructure and the Point of service (PoS) applications.

The level of complexity and requirement for privacy and security of individual health information, however, surpasses that of any other industry, resulting in different sets of terminologies, concepts and information standards, including the use of HL7 v3.

This is unique to healthcare and requires that existing solutions be customized to meet the pan-Canadian EHR standards. The idea of having a single point of access and integration for each jurisdiction's EHR infostructure is the principle behind the Health Information Access Layer (HIAL). The HIAL provides a highly scalable and extensible platform for connecting the many PoS applications with the various EHR components.

The Blueprint project uses the HL7 HDF methodology as a guideline to gather clinical business requirements into a set of use cases at increasing level of detail and then translate those use cases into a collection of high-level system design documents. Thus, the artefacts used to document the Clinical Work Processes are expected to be reusable uniformly within established standards and structured software engineering methodologies, such as HL7 HDF, IHE and others.

Information Security Requirements ISO/IEC 17799-1:2005 Code of Practice for Information Security Management is a widely adopted international standard for information security management.

Denmark

Responsible for the development and deployment of standards is the Danish healthcare organisation MedCom, which sets standards for IT systems, acts as a coordinating body to bring together healthcare providers, laboratories, vendors and others in order to develop interoperable standards.

Denmark's representative to the International Health Terminology Standards Development Organisation (IHTSDO) is the National Board of Health.

Relevant international standards exist in a number of areas in Denmark, for example classifications and terminologies such as ICD10, ICPC and Snomed CT.

There are also relevant standards for laboratory data and imaging (X-rays, etc.), for example the DICOM standard. Internationally, technical standardisation is performed by,

for example, the standardisation organisations ISO (global), HL7 (US) and CEN (European). MedCom's standards for communication of messages are based on CEN standards and are in widespread use in Denmark

Estonia

In Estonia, the eHealth Foundation and the Centre for Standardisation are responsible for the use of health informatics standards. The EVS (Centre for Standardisation) is a nonprofit association recognised by the Government of Estonia as the national standards body for Estonia. It started its operations as provided by the Technical Regulations and Standards Act in 2000. The eHealth Foundation are responsible for the promotion and development of national eSolutions within the healthcare system.

The following standards are mandatory for the provision of eServices in Estonia:

- HL7 V3 standards used in XSD files and extensions of the HL7 V3 XSD files
- eHealth projects, which are established on the basis of medical standards, mainly use XML, XSL and CSS files

In January 2010, Estonia became a Member of the International Health Terminology Standards Development Organisation to enable the use of Snomed CT in connection to digital health records, health research and other applications.

Hong Kong

There are some developments at individual organizations at specific domain areas. For example, the Hospital Authority has developed her corporate tables to support documentation of diagnoses, procedures, and drug data. The Department of Health is also maintaining a Compendium of Registered Pharmaceutical Products (Drug Compendium) which includes all registered drugs in Hong Kong. These small steps lay the foundation for building a standard terminology to support the eHR development – the Hong Kong Clinical Terminology Table (HKCTT).

The HKCTT will be built by integrating the international terminologies which are commonly used in Hong Kong, including SNOMED CT, ICD 10, and the Hospital Authority Clinical Vocabulary Table. Each concept in the HKCTT is mapped to SNOMED CT. For laboratory tests, they will be mapped to LOINC. The drug data will be built on the existing Drug Compendium which will be mapped to SNOMED CT.

HL7 and HL7 V3 Edition 2008 are used as the messaging standard for interoperability of

	messages.
Netherlands	Several organisations are responsible for the development and application of standards in the Dutch eHealth environment: One of them is Nictiz, as the national expertise centre facilitating ICT in healthcare. Nictiz is an independent foundation, mandated and largely funded by the Ministry of Health. It does not develop standards itself. Another organisation involved in standards is NEN (Normalisation and Standards Development). It is a non-profit organisation. Beside these two, HL7-Netherlands or IHE-Netherlands can be called exemplary.
	The Netherlands is member of the IHTSDO, the International Health Terminology Standards Development Organisation, where the Ministry of Health is a member and license holder. Nictiz is executing the activities.
	International standards used in the Netherlands:
	 HL7V2 is mainly used in regional and local communications, not for the national infrastructure HL7V3 is used as a standard for the communication using the national infrastructure Snomed CT is licensed by the Netherlands, and its importance in Dutch healthcare is growing. ICD9 is used in healthcare
	ICD10 is to be adopted. The intention of the ICD-implementation is that hospitals can use ICD-10 by at least at 01-01-2011. TN/ISO 13606 and the process of IME are not adopted as noticed standards.
	 EN/ISO 13606 and the process of IHE are not adopted as national standards, but when they have added value, they will be used as part of the national information structure
	Other standards like CCR (Continuity of Care Record) and Continua Health Alliance standards for RPM (Remote Patient Monitoring) are monitored to see when/where they have added value to be used as part of the national information structure in the future.
Sweden	Sweden has adopted different standards and is also a member of the International Health Terminology Standard Development Organisation (IHTSDO). The competence

centre in charge is the Unit for Classification and Medical Terminology at the National Board ofHealth and Welfare. The Unit works in collaboration with the Federation of the Swedish County Councils (CeHIS inte landstingsförbundedt), the National Centre for Patient Classification System, which was established by the National Board of Health and Welfare.

There are two projects carried out by the ministry that are connected to standards: The National Information Structure (2007-2009) and the National Interdisciplinary Terminology (2007-2011). Here stakeholders from the Swedish Association of Local Authorities and Regions (SALAR), health and social care principals and other actors in the field are involved.

The National Board of Health and Welfare is also Sweden's representative to the IHTSDO, where it leads the Swedish work on SNOMED CT. The translation of Snomed CT into Swedish is now finalised, and an organisation for implementing this on national level is now under preparation.

Beside SNOMED CT, Sweden has also adopted other international standards, such as HL7 v3, Tveksamt, DICOM däremot, EN 13606 and ICD 10. The Swedish translation for ICD 10 was created in 1997. The standard used for e-prescription is based on ENV 13607.

Privacy and Security

Australia

Individual privacy will be protected in accordance with identified legislative and policy requirements. NEHTA's Privacy Management Framework is being used to ensure that the national approach to IEHR takes privacy into account and demonstrates an understanding and awareness of privacy obligations and responsibilities. Where privacy requirements are set out in legislation, they will automatically apply to any contractual relationship in which personal information is collected and stored. The IEHR Service will maintain the privacy of an individual's data using a number of different mechanisms for authentication, access control, encryption, audit and complaints processes. Prior to implementation, a privacy implementation plan will also be rolled out.

The authentication of healthcare providers and healthcare provider institutions is critical to the successful implementation of the IEHR. A Public Key Infostructure (PKI) system is considered the most suitable basis for a solution to meet the authentication

requirements for healthcare providers. A high grade PKI system issues "digital certificates" after agreed identification and registration processes have been completed. The digital certificate is usually stored on a physical token such as a smartcard. PKI provides the basis for the authentication strategy for healthcare providers currently being developed by NEHTA.

Two NEHTA initiatives will contribute to this strategy. The UHI Program will develop a strong authentication solution for future e-health developments. The scope of this project included:

- Authentication of eligible healthcare professionals; and
- Authentication of institutions, including trusted data sources, reference data sources and healthcare institutions employing healthcare professionals.

An audit trail will record all activity on the IEHR, and will identify who accessed the IEHR, what they accessed and when they accessed it.

The national approach to IEHR is managed in accordance with NEHTA's Privacy Management Framework because it involves the collection and handling of health information. The IEHR Privacy Blueprint focuses on information privacy law requirements and individuals' privacy expectations. Other laws may have a significant impact on health information sharing, taking precedence over information privacy laws. These include laws that may prohibit specific information flows or authorise information flows that would otherwise be a breach of privacy legislation.

Examples include:

- Health services legislation;
- Freedom of Information (FOI) legislation;
- Public health notifications required under law;
- Child protection legislation;
- HIV AIDS legislation; and
- Mental health legislation

Belize

Hardware and software configurations present multiple layers of security to protect health information. They include use of firewalls, hypertext transfer protocols, usernames and passwords, audit trails and other features. Access codes provided to users are monitored continuously for abuse and additional security features continue to be added to ensure the integrity of the system.

Belize lacks the necessary policy and legal framework to permit enforcement of regulations relating to vital registration, disease notification, private sector reporting, and privacy of health information.

As part of the strategic planning a SWOT analysis was done that listed security breaches as a potential treat because the treat is higher with web-based applications like the BHIS. But the NHIS listed privacy and security as an important guiding principal in their vision, and will assure privacy of health information by continuously monitoring and upgrading the system to avoid unauthorised access to PHRs.

Canada

Privacy Requirements Ten privacy principles form the basis of the Canadian Standards Association's Model Code for the Protection of Personal Information (CAN/CSA-Q830-96), published in March 1996 as a national standard for Canada. Schedule 1 of the federal *Personal Information Protection and Electronic Documents Act* incorporates the CSA Model Code. These core principles facilitate an easily recognisable, principled approach to data protection in an EHR environment. The ten privacy principles, as they relate to PHI, are as follows:

- 1. Accountability for PHI
- 2. Identifying purposes for collection, use and disclosure of PHI
- 3. Consent
- 4. Limiting collection of PHI
- 5. Limiting use, disclosure and retention of PHI
- 6. Accuracy of Personal Health Information
- 7. Safeguards for the protection of personal health information:
- 8. Openness about practices concerning the management of
- 9. Individual access to personal health information

10. Challenging compliance

Information Security Policy: Each jurisdictional implementation of the EHRi will operate under a security policy appropriate to the jurisdiction and the features of the EHRi that are operational in that jurisdiction.

The four Canadian health information statutes are:

- 1. The Personal Information Protection Act, Alberta;
- 2. The Personal Health Information Act, Manitoba;
- 3. The Health Information Protection Act, Saskatchewan; and
- 4. The Personal Health Information Protection Act, Ontario.

Access Control: Access control includes identification of users during registration, their subsequent authentication during log in, and their authorisation prior to being granted access to services and data. Access control is intended to prevent unauthorised access to information systems; ensure the protection of services; prevent unauthorised computer access; detect unauthorised activities; and ensure information security when using mobile computing and telenetworking facilities.

There are so many issues related to access control that it is divided between a) user registration, b) user authentication during log in, c) and other aspects of user access control and authorisation.

Denmark

Generally, the Danish legislation has been very flexible with regard to healthcare reforms whenever legal provisions were perceived as an impediment to technological progress. However, in the latest national eHealth Strategy more attention is paid to the regulation of data security and patient privacy.

The most important legal initiatives necessary for eHealth are:

The separate rules contained in the Health Act regarding access for healthcare professionals to patient information stored in electronic medical records or registers; The rules contained in the Health Act regarding access to registries concerning medicine and vaccinations; The separate rules in the Consolidation Act on Legal Protection and Administration in Social Matters regarding automatic electronic exchange of information between the hospitals and home care services consolidated in

August 2007, and the revised health act paragraph 37 on patient's right to see own data.

Up to this point, legislation determines which types of healthcare professionals have access to which data and the conditions to be met before access can be given. Thereby, the Danish Data Protection Agency monitors all activities regarding the Act on Processing of Personal Data.

Since the Act on Processing of Personal Data entered into force in 2000, the Act has been amended several times - most recently on July 1st 2007. It is important to always read the Danish Act on Processing of Personal Data together with special, supplementing provisions in other Acts. The Danish Health Act (2007) specifies the rules for transfer of data to healthcare professionals. It distinguishes between the disclosure of health information to other healthcare professionals in connection with treatment and care, collection of electronic medical data in connection with treatment and care and disclosure of health information for other purposes. There are special rules concerning disclosure of health information for scientific and statistical purposes and disclosure to third countries.

Finally, the Danish Board of Health issued legal guidelines regarding the liability and other legal matters in connection with practitioners' use of telemedicine. The guidelines refer to rules and principles in the existing legislation which also applies in connection with the use of telemedicine. The guidelines conclude that the use of telemedicine does not affect the usual legal liability and other legal obligations of Practitioners

Estonia

The Personal Data Protection Act (PDPA) was passed by Parliament in June 1996 and entered into force on 19 July 1996. The Act was amended in 2003 to be made fully compliant with the EU Data Protection Directive 95/46/EC. The PDPA's lastly amended version came into force on 1 January 2008. The Act protects the fundamental rights and freedoms of persons with respect to the processing of their personal data, in accordance with the right of individuals to obtain freely any information that is disseminated for public use.

In 2008, a revised version of the Act introduced several changes: First, the previous classification of personal data into three groups (non-sensitive personal data, private personal data and sensitive personal data) has been replaced by two data categories:

(1) "personal data" and (2) "sensitive personal data", the latter being the sub-class under special protection. Moreover, the new PDPA Act extends all general principles applying to the processing of personal data to the processing of the personal identification code (the unique number assigned to every Estonian citizen and resident). Lastly, the new Act contains a new definition relating to the "person liable for the protection of personal data" while regulating the processing of personal data for research and statistics purposes.

Hong Kong

Data privacy and system integrity and security are of paramount importance in the development of the eHR sharing system. Food and Health Bureau (FHB) will conduct, in collaboration with the Office of the Privacy Commissioner for Personal Data and the Office of the Government Chief Information Officer amongst others, Privacy Impact Assessment, Privacy Compliance Audit, Security Risk Assessment and Security Audit, covering a wide range of issues.

The long-term legal protection for data privacy and system security will also require exploration and formulation of a legal framework, having regard to current legislative provisions applicable to personal health data and overseas experience. These tasks will be taken up by the dedicated eHR Office and require dedicated directorate support for high-level input to address the complex policy and legal issues involved.

Netherlands

The patient rights for electronic data are based on the same rules applied to paper data. At the national level, an electronic patient record is automatically created if the citizen does not object to it (opting out model). But patient consent is needed for various usage of data:

- 1. Patients need to consent by consultation to the inclusion of medical data in their national record on a case by case basis;
- 2. In current although disputed legal projects regarding EHRs, patients can demand the deletion of data from their healthcare record;
- 3. Patients can demand the deletion of the entire healthcare record;
- 4. Patients can bar certain healthcare providers from access to the healthcare record and
- 5. Patients can hide certain types of information on their healthcare record and
- 6. Patients can also get access to the logging of the use of their own data (whom looks at what).

Sweden

The "Patient Data Act" from July 2008 is the most recent regulation dealing with patient data in Sweden. By replacing the Patient Record Act and the Health Care Register Act, the Patient Data Act constitutes a change in the law.

On the one hand, the new law enables care professionals to digitally access a patient's entire care history from different levels within the health and medical care services and provides a nationwide share of locally stored information.

On the other hand it strengthens citizen participation by enabling to determine, who is to be given access to their overall medical record and showing what personnel had access to medical records. It should be noted that access to medical data from other care providers always requires patient consent. Further the patient can block certain data from being shared.

Apotekens Service's processing of personal data in the national database for eprescriptions and the national database of dispensed drugs is governed mainly by the Act of the Prescription Database41 as well as the Act of Medication Summary42.

eCards

Australia

NEHTA has identified that, at this stage, healthcare individuals will require one-factor authentication (subject to the level required by Australian Government e-Authentication Framework (Individuals) framework); and providers will require two-factor authentication (ie. digital certificates delivered on smartcards). NEHTA may need to test whether these levels of authentication strike the right balance.

A high grade PKI system issues 'digital certificates' after agreed identification and registration processes have been completed. The 'digital certificate' is usually stored on a physical token such as a smartcard. PKI provides the basis for the authentication strategy for healthcare providers currently being developed by NEHTA.

Belize

No eCards or smart card technology has been implemented as part of the EHR in Belize. This does not mean that it could not be implemented in the future but currently not plans exist.

Canada

No eCards or smart card technology has been implemented as part of the EHR in Canada. This does not mean that it could not be implemented in the future but currently not plans exist.

Denmark

The CPR-number is however not incorporated in an identity card. As an identifier the in 2007 introduced Health Card is used. The Health Card substitutes the social security card and contains the patient's CPR-number, name and address, name of his doctor, social security category and municipality. Apart from being an identifier – used not only in healthcare – the card also gives access to healthcare free of charge.

The Danish government has decided to adopt an official digital signature as an alternative to electronic ID cards. Reasons for this decision are connected to pragmatic technical and economic choices, as the digital signature is said to be not the most flexible or secure form, but is expected to achieve widespread uptake more rapidly than other solutions and moreover is a cost effective approach.

Thereby, the goal is to enable all Danes to conduct their business with public authorities securely from their home computers, using the same identification system for all eServices without having to pay additional charge for providing their identity or having to carry an eCard. In general, citizens can get free, software-based "official" digital signatures e.g. to access the portal Sundhed.dk and other secure websites containing personal information (taxation, housing etc.).

Sundhed.dk was launched in 2003 and acts as a single access point to healthcare services for both citizens and professionals. Citizens have access to both information and communication with the entire healthcare service through the web portal and it provides a framework for communication between citizens and professionals as well as between professionals.

Estonia

Estonia began issuing ID cards in January 2002 and has since issued over 800.000 cards: the largest ID card roll-out in the EU. The card, which is valid for 10 years, is used for identification but also as a travel document within the EU. ID cards are used for visual identification of persons, to access different services, for electronic identification and for digital signatures and can be verified against the Population Registry.

Because of the concept of the Estonian ID-card, according to which the smart card itself does not contain any other information than that necessary for the identification of a person, there is no longer need for a special health insurance card. A person identifies with his/her ID-card, while the information about his/her insurance is maintained in the respective database.

The roll-out of the ID-cards was completed in 2006. The next phase – getting people to use it electronically – started with the initiative "Computer Protection 2009". The growth of usage is expected to take place in forthcoming years.

Up to this point, the ID cards are used as identification tool for electronic services provides over the "eesti.ee" portal. Prospective initiatives include a public tender for new generation ID-cards within this year. Plans include the transformation from Orga/Micardo platform to MultOS and including RFID capability (with separate chip) for biometrics. Compliance with the European Citizen Card standard is also considered. Furthermore, all three major mobile operators in Estonia are now providing Mobile-IDs for authentication purposes

Hong Kong

From 23 June 2003, only Smart ID cards were issued .Between August 2003 to 2007, all Hong Kong ID cards were replaced.

On 23 June 2003, the Immigration Department of Hong Kong began issuing a new revised Smart Identity card. The smart identity card is the size of a standard credit card, and is made from polycarbonate, a durable material strongly resistant to environmental influences as well as mechanical, chemical and thermal stress. The card is embedded with an integrated chip that stores and processes data.

The 'chip' in the smart identity card allows it to record, store, process and transmits data to and from designated devices. It has segregated compartments that keep immigration-related applications separate from value-added non-immigration applications.

There are two types of smart identity card:

 The Hong Kong permanent identity card, which states that the holder has the right of abode in the Hong Kong Special Administrative Region (HKSAR) The Hong Kong identity card, which does not state that right

The benefits of using a smart identity card are as follows:

- High security data are engraved into different layers of the card and stored in the 'chip', which helps to prevent lost or stolen cards from being altered or used by other people.
- Greater convenience the card may be used in various non-immigration applications: for instance, as an e-Certificate or a library card.
- Quality service the smart identity card is the foundation of the delivery of electronic government services. In future, smart identity card holders will be able to enjoy various kinds of public services simply by going on-line at home or making use of smart identity card readers without having to attend government offices in person.
- More travel convenience with the thumbprint templates stored in the chip of the identity card, holders can enjoy more convenient immigration clearance via the e-channels of the Automated Passenger Clearance System and the Automated Vehicle Clearance System.

Netherlands

Citizens in the Netherlands have no eCard. They have an insurance card on which the identification number BSN is also stored, but it is an old-fashioned, plastic card distributed by insurance companies. It contains the EU-format for insurance cards on the back of the card. This insurance card is not used for data exchange, payments or administration.

However, the goal was to have a national electronic ID card for citizens, the so-called eNik, also for use in the healthcare sector, especially for patients to access their own medical data. The introduction of the eNik is troublesome. It was planned for 2006, but may not become available before 2012 or beyond.

Now for patient record access other options are used/ have been developed. Security mechanisms concerning the identification of patients are in place in the Netherlands.

First, there is the "DigID", the Digital Identity, which is a system that is shared between cooperating governmental agencies, allowing digital authentication of the identity of a person, who applies for a transaction service via internet. In addition there is SMS verification. The eNik plans security mechanisms through a PKI. The PKI is a public key infrastructure, which describes a system that provides users of electronic

communication services with digital key pairs, consisting of a private and a public key. As it is planned that patients have access to their EHR, a face to face control is planned.

Discussions are taking place about where this should be taken.

Given the fact that eNik is not available yet, the biggest challenge is the secure authentication of citizens: DigID, SMS and face to face control has been set up, which is a complex and labour intensive process. Challenges lie in all areas, from regulation to implementation.

The discussion is urgent because patient access remains a precondition for a national rollout of the electronic health record and is therefore crucial. Until this question is settled, full roll-out of the electronic health record will be slowed down.

Sweden

As part of the identification of patients and professionals, eCards are used in Sweden. Citizens and patients can use the eCard nationwide since 2005 for different purposes: They can make use of the ID card to communicate with healthcare services, such as confirming age and proving identity when collecting prescription medication at a pharmacy. Additionally the eCard can also be appointed to pay in a shop or conduct banking business.

Beside the role of providing biometric data, it is planned to embed an electronic circuit in the eCard, which will be able to carry electronic information – so-called electronic ID services (e-ID) – and thus identify the bearer electronically. The goal set out by the Swedish government is to achieve a national, cross-sectoral e-ID solution capable of ensuring secure electronic identification when eServices are used.

It is required to possess the above mentioned personal identity number and be over the age of 13 to apply for an eCard. Applicants under 18 must have a parent/guardian's consent to apply.

Since 2009 there is also an infrastructure for the secure identification of healthcare professionals through so-called directory and smart cards. The implementation process of the distribution of about 205 000 cards is ongoing and planned to be finished by the end of this year. The framework for the system is provided by SITHS, which in Swedish stands for secure eHealth: In this model, health and social service employees have a personal electronic ID card with an electronic Public Key Infrastructure certificate (PKI).

This enables care professionals to confirm their identity and authorisation. This has been so far applied in 15 of 21 county councils and 8 municipalities have joined.

Stake holder Buy in or Resistance

Australia

According to the National E-Health strategy finalised in 2008:

The national consultation process established that there is a consistently strong level of support for the importance of E-Health across all parts of the Australian health care sector.

Stakeholders clearly recognise the potential and need to better use IT (Information Technology) to improve the efficiency and quality of health care delivery and the pressing need to improve the flow of information across the health system. There is a strong view that, without national coordination, initiatives will only respond to localised needs and the broader benefits of E-Health on a national scale will not be realised.

Belize

It was observed that service providers outside the public sector have so far not shown great interest in linking-up or sharing data with the BHIS. They cite concerns over privacy and security of patient information in addition to possible use of data (by government) for tax purposes. Besides, connecting to the BHIS will entail additional hardware and software cost for which little benefit is perceived. To enhance buy-in, the BHIS would need to demonstrate value to the private sector. To the effect, the NHISC will:

- a. Identify physician champions of the EHRs in the private (and public) sector to further advocate on the benefits of EHRs.
- b. Leverage the "persuasive" power of the NHI, which has financial/contractual relationship with private sector providers (the relationship is likely to grow stronger as coverage by NHI expands)
- c. Ensure appropriate legislation to back-up request for information; this can enhance compliance where combined with incentives.
- d. Provide incentives to private and NGO facilities that collaborate with the MOH on the development of the NHIS – measures to consider include (i) free installation of the EHR software (ii) training on use of BHIS modules and dashboards (iii)

participation in CME activities via telemedicine

- e. Develop excellent customer relations private sector providers can be very sensitive to productivity losses that arise from installation of EHRs as well as subsequent system malfunction
- f. Encourage NGO/private sector representation in the NHISC

Canada

The health sector in Canada was one of the first industries to embrace the use of computers and information systems to support administrative, human resource management, financial, and other operational needs. That history of commitment to using electronic information management is now being applied to include clinical information in primary care, long-term care and community-based care. In addition, this clinical information must be integrated in the program-level and overall decision making processes of healthcare administrators and policy makers. In one sense, we already have EHRs in Canada. In fact, a very large number of clinical applications exist in operation today in hospitals, clinics and physician offices.

In the past 20 years, the emergence of systems to support clinical information (CIS) in the areas of radiology (RIS), lab orders and results (LIS), and prescription drugs (DIS) has provided increased capabilities to support the clinical needs of providers and their clients/patients, primarily in the acute care sector.

Denmark

Furthermore, financial incentives for health IT adoption by healthcare providers are an effective policy tool to spur the use of health IT. In Denmark early efforts to computerize medical practices relied on financial incentives. In the 1980s for example, primary care physicians received small subsidies for submitting medical claims electronically by disk. Denmark has also set national reimbursement rates for email consultations and in 2008 had over 20.000 e-mail exchanges per month between patients and doctors.

Estonia

The success of the EHR with medical institutions can be seen by the immediate volume of use: more than 350 000 medical documents were sent to the EHR during 2009.

Altogether 953 GPs, private healthcare specialists, and hospitals connected to EHR during the first year, which is 90% of all healthcare institutions in Estonia. By the end of 2009, 143,360 citizens had a medical document in the EHR. This number has increased rapidly with an additional 114,012 citizen documents added by January 1st 2010,

meaning that 20% of citizens had some kind of medical record in the EHR. This rapid increase is down to the launch of digital prescriptions.

The uptake has been somewhat slower with citizens. A web-based Patient's Portal was launched on October 26th 2009 to allow citizens to access data in the EHR. In the first five months the portal was visited by 12,993 citizens. This is 1% of the Estonian population, as of January 1st 2010. The reason for this sluggish uptake lies in the promotion of this access.

There has not yet been any publicity released directly by the government on how to use the portal. Rather, it has been doctors who have been informing their patients.

Hong Kong

The participation by healthcare providers, IT service providers and other stakeholders in the private sector, as well as the general public, in the eHR development process is essential to ensure its successful deployment in the private sector and acceptance by the community.

The Government will launch an eHR Engagement Initiative with all relevant stakeholders, and invite them to submit proposals on

possible partnership projects that could facilitate the development

and deployment of electronic medical/patient record (eMR/ePR) systems and contribute to eHR sharing in the private sector.

At the same time, the Government will also need to initiate public consultation on specific eHR issues especially those affecting data privacy and legal protection, e.g. consent model and access control based on the principle of voluntary participation. These tasks will also need to be undertaken by the eHR Office and this is envisage the need for a high-level steer to ensure comprehensive and meaningful engagement process and proper use of capital public resources in support of eHR development in the private sector.

Netherlands

In terms of infrastructure, 99% of Dutch GP practices use a computer. Almost the same share, that is 97% of the practices, utilises an Internet connection. In the Netherlands, broadband represents the most common form of access to the Internet with 82% of GP practices utilising broad-band connections.

With regard to the availability of a computer in the consultation room compared to the actual use of the PC in consultations with the patients, there is nearly no difference as both availability and use are nearly universal (99% of practices and 94% of practices respectively).

The storage of electronic patient data is common practice in the Netherlands. All types of medical patient data are stored in digital form in more than 90% of GP practices.

In the Netherlands the use of electronic networks for the transmission of medical patient data is well established and widespread. 84% of GP practices receive analytic results from labs and moreover 26% exchange data with other healthcare providers. The Netherlands shows exceptionally high usage rates when it comes to the transfer of any kind of medical patient data, as well as with regard to the transfer of administrative patient data. Especially remarkable in the Netherlands is the high occurrence of ePrescribing which is used by 71% of the practices.

The further deployment of the system will depend on different issues, one of the most important being financial compensation for connecting to the national hub.

Sweden

No direct information about resistance from Physicians in Sweden could be found.

National ePrescription has been a common routine in Sweden from before 2000 and has a take-up of 80%. This can be seen as an indication that the physician community is not against converting to electronic data and using of IT in health care.

Summary

As part of their eHealth strategy each country made the decision to implement an EHR, although they may be in various stages of the implementation they share the concept of an electronic health record amongst them. In the projection phases the EHR was given a name by each country in their native language and in broad terms defined what would be included in the EHR to achieve the needs of the country.

The form of the EHR is the only factor that makes each country case unique to its origin; Australia wants a PEHR, with a clear focus on patient involvement from the start but Denmark only move into patient access as a last phase.

In chapter 2 the literature review discussed some author's perspective about various key success factors during the implementation of an EHR. In chapter 4 the analysis was based on the same key success factors for the eight country cases. It was clear through the data collection for these cases that the key success factors played a significant role not only in the implementation project by also for the eHealth strategy for the country.

This analysis only covered five of the most common key success factors in EHR implementation, but the potential exist for further studies to cover the extended scope of the study.

In chapter 5 the results will be discussed not only in the context of the cases against one another but also with the South African environment.

Chapter 5

Result analysis discussion

Introduction

The prominent key success factors; funding or cost, unique patient identifiers; standards, privacy and security/confidentiality and the stakeholder buy-in or resistance have been covered in the literature review in chapter 2, and formed the categories for the analysis in chapter 4.

This chapter will look at what was learned and evaluate these factors against the South African environment, under the same categories.

Funding:

It is not surprising that the estimated budget for a project of this magnitude ranged into several million, or billion in the case of Canada, in currency. The return on investment does not only take on the form of currency saved by the patient in reduction of duplication tests and medication, or even worst hospital admission due to treatment errors cause by incomplete records, but also save physicians time that can be converted into revenue due to an increase in patients seen per day.

Each project budget consists of an initial investment and then additional supplementary investments over years example 5 years. Sources of funding were primarily government invested with the exception of Belize using loans and grants to subsidise their project and Estonia using funds from the European Union to develop their eHealth strategy. Although the governments of these countries were not the primary sources of funding it invested not only funding from the annual budget but also in the form of infrastructure i.e. building, IT technology etc. The government of Denmark and Netherlands were the primary investor but has additional funding from other stakeholders like private insurance companies (Netherlands).

The EHR implementation was initialised but no formal budget was allocated for this project. Academics from the University of Kwa-Zulu Natal, involved in telemedicine commented that the EHR project has been temporarily suspended for the current

time, no formal announcement has been made. In August 2011 the Health minister Aaron Motsoaledi submitted the final draft of the National Health Insurance (NHI) for South Africa to parliament, and it was accepted. This bill will launch South Africa into a Health financing reform, with the intended goal of the NHI making health care available to all people of South Africa as a single payer model and not the current two tier model currently in use. The NHI model indicates that resource requirements under this model increases from R125 billion in 2012 to R214 billion in 2020 and R255 billion in 2025 if implemented gradually over a 14-year period.

Unique patient Identification:

A strong consensus can be formed on the information collected on the unique patient identifiers, it is essential to identify the patient correctly not only for medical reasons but to achieve a longitude record with a one record to one patient ratio. Identification numbers only get assigned at the age of 11 or 18 in countries like Hong Kong and Belize, which makes a different unique patient identifier essential in the implementation of an EHR. Denmark, Sweden and Netherland have a national identification number, issued at birth, which is used for not only in the health sector but other government divisions as well.

Australia, due to a lack of a national identification number, has launched a subproject to create a registry for both individual (IHI) and Health Care providers (HPI). Canada however found that each province/territory was assigning multiple identifiers to a single patient, a common identifier scheme was lacking across all levels of jurisdictions, and an Enterprise Master Patient Index (EMPI) has been set-up to act as a registry.

The Patient Registration and the Master Patient Index (MPI) were identified as the main applications that are the repository of the core patient information for eHR.ZA. All patient related systems and applications should be linked to the MPI that will form the national patient database.

South Africa has a national identification number that can be used as the unique patient identifier. Some vendors have used the current Identification format and build a validity check, to avoid invalid numbers. It is however concerning that South Africa had an increase in counterfeit identification documents in the last 5 years. Currently the Green Identification book and the South African driver's license card are both

accepted as methods of identification in South Africa. The eHealth strategy for the EHR in South Africa the eHR.ZA discussed smart card technology; this will be discussed in more detail in the eCard section, however the smartcard technology will be ideal to incorporate all these cards into one.

Standards

Standardising has been a term used by all countries in their eHealth strategies, the standards that were adopted may be different but the concept of standards is the same across the board. NIHCRR (2006) defined a 'standard' as 'established by consensus and approved by a recognized body that provides rules, guidelines, or characteristics for activities.

International standards that are most frequently adopted:

- ICD 9 or 10 International Classification of Disease
- SNOMED CT Systematized Nomenclature of Medicine Clinical Terms
- DICOM Digital Imaging and Communications in Medicine
- LOINC Logical Observation Identifiers Names and Codes (for identifying laboratory and clinical observations)
- HL7 and HL7 Version 2 or 3 Health Level Seven International (**HL7**)
- EN/ISO 13606 or other ISO standards International Organization ofor Standardisation

A requirement shared by all countries is the need for standardisation, the implementation of an EHR has highlighted the need for standardisation to achieve interoperability. In data collection for Belize I could not find direct confirmation which international standards were adopted, but the Licensing and Accreditation Standards for Hospitals and In-patient Health Facilities published by the MOH (2009) set the standard operating procedures for facilities with sections for patient-centred standard and Health Care Organization Management Standards amongst others. It may be easier to get compliance in Belize due to the smaller population number, but Belize will have an advantage if the procedures in all facilities are consistent.

Interoperability is an important consideration, as the nine Provinces use five different major systems, where a fair amount of the facilities are not IT compliant at all. South Africa is a member of ISO/TC 215 Health Informatics. Several standards are in use to promote interoperability and data interchange. South Africa has adopted ICD-10

as the national diagnosis coding standard. HL7 version 2.4 has been adopted as the national messaging standard in the public sector.

The final international standards have not been decided upon but according to the EHR Strategy, a selection of technical standard would be considered as stipulated by ISO standards.

Privacy, Confidentiality and Security:

The issue of privacy and confidentiality is a concern not only for the patients protecting their right to privacy but also to the physicians to protect their patient's confidential information. All the case countries not only have national legislation that protects the individual but also special policies for the EHR, but in Estonia the legislation was correctly reviewed and amended to accommodate the inclusion of the EHR. Australia and Canada passed a privacy and confidentiality framework as a national standard; these are implemented alongside the EHR and include security measures as well.

These measures are vital to not only the survival of the EHR but also to the starting of the EHR. Patients as a general accepted norm would have to give consent for their health information to be included in the electronic records, if there are any concerns about the security of the data no patient will give consent.

The requirement of privacy and confidentiality does not stand alone and can be added to the unique patient identifier theme where most of the case countries except Belize are moving to the patients having access or managing their own health record, this has to be controlled by user authentication. Several countries have or are planning on implementing the Public Key Infostructure (PKI) technology to handle the authentication of not only the patients especially where smart card technology is used but also the health care providers that use the system.

In the Netherlands a patient has the right to object to inclusion of data in the record, this is referred to as the opting out model. Patients can demand the deletion of data from their healthcare record; or demand the deletion of the full record. This issue is disputes and in my opinion rightly so because a patient may exclude information on

a sexual transmitted disease due to possible embarrassment to the patient but the possible contra-indication to medication can be life-threatening.

The policies of privacy and confidentiality are not seen as a separate entity and are highly intertwined with the implementation of standards. These standards usually include access control, authentication, audit trails, consent etc. However all measures will fail if the national legislation is not updated to an electronic era.

Appendix 1 includes the list of the national legislation to be taken into account for the eHR.ZA. However this will not be sufficient for the implementation of the EHR in South Africa, project scope will need to determine the security requirements of the data elements and include security and confidentiality standards.

According to the eHealth Stategy the following should be taken into consideration:

- User /access rights- hierarchies
- Access should be to sections of a record, not to all of it, according to the needs of the user. Clerk does not have access to everything that the doctor can see for example.
- Patient consent
- Authorisation
- Data security and safeguarding
- Digital signatures
- Data encryption
- Establish period when records will be updated on discharge and during working hours (if not real time integrated system)
- Audit trails of who has accessed what information.
- A major issue is staff education as to how staff handles records.
 Organizational policy is critical to this if people are automatically disciplined
 or fired for breaching confidentiality, it will not be breached. Medico Legal
 considerations need to be addressed.

eCards

The role of eCards differ from Country to Country with some like Belize and Canada not having eCards or plans to implement eCards in the near future. Australia is implementing eCards for the providers who require two-factor authentication (ie. digital certificates delivered on smartcards), but will have no plans to use eCards for individuals identification yet.

The Danish government had an interesting twist on the eCard phenomena by deciding to adopt an official digital signature as an alternative to electronic ID cards. These will give citizens access to multiple public authorities with the digital signature as authentication.

The case countries that use eCards differ from single function, Estonia with a smart card that has no additional information other than necessary for identification of a person, and the digital signature to a comprehensive suit. Hong Kong has a comprehensive suit that allow the eCard to be used by as an identification card (Immigrant applications) but can also by Non-immigrant application for example library card. However Sweden has taken it step further and included the use of the ID card to communicate with healthcare services, such as confirming age and proving identity when collecting prescription medication at a pharmacy, and can also be appointed to pay in a shop or conduct banking business.

South Africa has expressed the intention to implement smart cards not only for identification by also for the storing of health information on the embedded chip that will be Read by or Written to by Clinics of Hospitals. Biometric (fingerprint) identification and smart card were said to be the best solution in the short to medium term. The value in using smart card is associated with its ability to be used online and offline, enabling the use even by health clinics in rural areas where there is no access to telephone lines.

Stakeholder Buy-in or Resistance

Stakeholder buy-in is usually easier to measure due to the fact of it being measurable to the amount of users using the system. Resistance to any electronic system is normally propagated by some users are often not a true representation of all the stakeholders.

Australia, Canada and Netherlands already have a high percentage of practices that converted to computer and information systems in the heath care sector, having reduced the resistance against the electronic era helps to convince the providers of the potential benefits. Belize has started the BHIS in the public sector only and has not seen much interest from the private sector; the campaign for changing this is marketing benefits and initiating an incentive for collaborating with the MOH, incentives have been proven to be success by Denmark. Estonia's medical community has taken up the challenge to using the EHR but the patients have not shown much interest, mainly due to the lack of communication from the government on the subject. Hong Kong has done a transparent strategy with public interest as the main focus; public input has been encouraged during the process for example the public was asked about their concerns about the privacy and confidentiality of the EHR.

In South Africa we are bound to have a full suite of resistance to the EHR, this will include amongst others; a) Computer literacy; b) Resistance to high cost of infrastructure required for own pocket expenses; c) Privacy and confidentiality concerns. But in my opinion the main reason will be the perception of more work for the physician not justifying the benefits; this however will have to be propagated from the top (government) down.

Summary

The literature review (chapter 2) discussed the opinion of academics on the factors important in implementing an EHR. In the case countries we reviewed 6 main topics being; funding, unique patient identifier, standards, privacy and security, eCards and stakeholder buy-in. From the analysis it is clear that each one of these factors is

essential in the implementation of an EHR, but more importantly they are not mutually exclusive from one another.

Privacy, confidentiality and security is probably one of the main factors that can make or break an EHR implementation, this factors link to several of the other factors; unique patient identifier, standards and stakeholder buy-in. The main stakeholder in an EHR implementation is the Government of the country where it is implemented; they do not only control legislation but need to pass the initiative to start a national EHR project and allocate funding.

The standards that need to be implemented are not only for international standard to ensure uniformity on technical and clinical terminology, but include the processes at health facility level as well.

eCards have shown to be essential to the implementation of the EHR for the counties that uses it, but the need for eCards is subject to the role defined in the scope of the EHR implementation.

The Conclusion in the next chapter will look at the South African environment and answer the research question of whether South Africa is ready for a National Electronic Health record.

Chapter 6 Conclusion

In chapter 5 we concluded that the following factors are essential for an EHR implementation:

- Funding
- Unique Patient identifier
- Standards
- Privacy, confidentiality and security
- eCards (subject to project scope)
- Stakeholder buy-in

These factors can form the basic blueprint objectives in a guideline for not only the South African implementation of an EHR but any national initiative. As seen in the results the case countries had several ways to achieve the same outcome on all of the above listed factors, this highlights the fact that there is not a right or wrong but a requirement to contextualise the factors in the country environment.

The 8.3% of GDP spent on health is split as 4.1% in the private sector and 4.2 % in the public sector. The 4.1% spend covers 16.2 % of the population, (8.2 million people) who are largely on medical schemes. The remaining 4.2% is spent on 84% of the population (42 million people) who mainly utilize the public healthcare sector (Department of Health of South Africa (DOHSA, 2011).

The NHI project has been approved and will be completed over a 14 year period, and is intended to bring about reform that will improve service provision. It will promote equity and efficiency so as to ensure that all South Africans have access to affordable, quality healthcare services regardless of their socio-economic status.

In the policy paper for the NHI (DOHSA, 2011) it is stated;

'significant improvements in health services coverage and access since 1994 have been achieved. However, there are still notable quality problems. Among the commonly cited and experienced by the public are: cleanliness, safety and security of staff and patients, long waiting times, staff attitudes, infection control and drug stock-outs.'

The question will have to be raised if these two projects (and EHR and NHI) will be able to run at the same time with an already extensive funding proposed for the NHI initiative alone. If a loan was acquired from the WHO or development banks the financial burden will lighter and these projects can run simultaneous.

When one needs to consider the implementation of an EHR in the public sector, as is the proposed plan for the initial phase and then move to the public sector, you will have to consider the amount of different information system vendors in the public sector alone:

Medicom: KZN, Gauteng, Limpopo

Nootropics: Northern Cape

• Clinicom: Western Cape

• Meditech: KZN, Free State

Unicare: Western Cape, Limpopo, Eastern Cape

Unfortunately there is not 100% coverage of any of the systems in any province, due to several factors being illiteracy, electricity, and broadband coverage to mention a few. Mars and Seebregts (2008) reported literacy of people over the age of 15 years is estimated to be in the region of 80 - 85%. It is suggested that 30% of adults are functionally illiterate. There are 11 official languages and many people who are literate in one will not be literate in the others. Internet usage is low, 109 per 1000 people and the relative cost of internet usage is about 25 times that of the USA. There is little health related material available on the Internet in 10 of the 11 official languages.

The Infrastructure to allow the EHR to be possible will be a significant exercise that can cost billions. Hardware infrastructure does not include just the rural areas that do not have any computers but in some cases have no electricity for extensive periods of time, and have no broadband coverage in many areas. Extensive work has been done in the last two years to improve the broadband coverage in South Africa. In the

As mentioned in chapter 5 South Africa is a member of ISO/TC 215 Health Informatics. South Africa has adopted ICD-10 as the national diagnosis coding standard. HL7 is the accepted national messaging standard in both the public sector and private sector.

Extensive standardisation of process and procedures will have to done at a national level, currently provinces take guidance from the National Department of Health but manage most of their processes and procedures at a provincial level making for 9 different standards, one for each province. The Departments of Health in each of the nine provinces are responsible for individual health information systems and telemedicine in their province.

Both the NHI and the EHR are both effectively part of the planned health reform and the eHealth strategy for South Africa. The NHI will have a positive impact on quality of health care in the public sectors. It would be the ideal to run these projects together because they share so may key factors that are essential to achieve success in both projects. When planning the infrastructure for IT its essential to consider the big picture to ensure the sustainability of the health reform.

The current South African (SA) environment does not allow the country to be ready for a national electronic health record. The lack of eHealth capability does not justify a national initiative of such a magnitude. There is a presence of information systems in the provinces but the scale tips more to hospitals and facilities not having any electronic equipment or information systems.

The potential however is overwhelming and the benefits will surely justify the cost of the implementation, but the provinces need to improve the coverage of the information systems and improve computer literacy at provincial level before a national effort can be made to have a single national electronic health record. An EHR aims to be as comprehensive and complete as possible and will not be complete if all the health institutions in the public sector are not included.

Appendix 1:

Legislation

The Strategic framework stated the following as relevant legislation to consider during the implementation of the EHR:

Constitution of the Republic of South Africa No 108 of 1966/7

Chapter 2 Bill of rights – Section 7 – Enshrines the rights of all people in our country and affirms the democratic values of human dignity, equality and freedom.

Health Act

Section 13, Obligation to keep a record – Subject to National Archives of South Africa Act, 1996 (Act No 43 of 1996), and the Promotion of Access to Information Act, 2000 (Act No. 2 of 2000), the person in charge of a health establishment must ensure that a health record containing information as may be prescribed is created and maintained at that health establishment for every user of health services.

Medical Schemes Act

There are detailed regulations that come under the Medical Schemes Act that are intended to protect the patient, but medical schemes are currently getting access to private medical information. [AK]

Electronic Communications and Transactions Act, 2002, no. 25 of 2002, section 13

Extracted from the regulation published in 2002:

1. Where the signature of a person is required by law and such law does not specify the type of signature, that requirement in relation to a data message is met only if an advanced electronic signature is used.

- 2. Subject to subsection (1), an electronic signature is not without legal force and effect merely on the grounds that it is in electronic form.
- 3. Where an electronic signature is required by the parties to an electronic transaction and the parties have not agreed on the type of electronic signature to be used, that requirement is met in relation to a data message if
 - a. A method is used to identify the person and to indicate the person's approval of the information communicated; and
 - b. Having regard to all the relevant circumstances at the time the method was used, the method was as reliable as was appropriate for the purposes for which the information was communicated.
- 4. Where an advanced electronic signature has been used, such signature is regarded as being a valid electronic signature and to have been applied properly, unless the contrary is proved.
- 5. Where an electronic signature is not required by the parties to an electronic transaction, an expression of intent or other statement is not without legal force and effect merely on the grounds that
 - a. It is in the form of a data message; or
 - b. It is not evidenced by an electronic signature but is evidenced by other means from which such person's intent or other statement can be inferred.

This legislation regards the electronic signature as legal, but this legislation is in direct conflict with the Medicine Control Act.

Health Professionals Council of South Africa's Ethical rules:

Rule 15 of the HPCSA's ethical rules states that:

"Any student, intern or practitioner who, in the execution of his or her professional duties, signs official documents relating to patient care, such as prescriptions, certificates(excluding death certificates) patient records, hospital or other reports, shall do so by signing such document next to his or her initials and surname in block letters."

On the issuing of prescriptions, Rule 17 states that:

"A practitioner -

- a. shall be permitted to issue typewritten, computer-generated, pre-typed, preprinted or standardised prescriptions for medicine scheduled in schedules I,II, III and IV of the Medicines and Related Substances Control Act, 1965 (Act No. 101 of 1965), subject thereto that such prescriptions may only be issued under his or her personal and original signature;
- b. shall issue handwritten prescriptions for medicine scheduled in schedules 5,6,7 and 8 above of the Act referred to in paragraph (a) under his or her personal and original signature (see also rule 14)."

Appendix 2:

The South African Department of health concluded that the following would make up the content of the Electronic Health Record of South Arica, also called eHR.ZA

Demographic data

- a. Names
- b. DOB/Age
- c. Gender
- d. Nationality
- e. Address (not clear how many should be captured)
- f. Telephone contact (s)
- g. Family linkage (may be of epidemiological use)

Major medical events

- 1. Parity/Gravidity
- 2. Genetic markers
- 3. Pre-dispositions to illness
- 4. Current treatment
- 5. Blood group
- 6. Allergies
- 7. Donor status
- 8. Episode history
 - a. Sorted by encounters, reverse chronological order:
 - i. Facility or institution ID
 - ii. Care provider ID
 - iii. ICD-10 diagnoses
 - iv. Procedures (CPT-4 or other agreed standard)
 - v. Discharge summary at the present time, this would be in free-text format. A separate project should look at structured medical data.
 - vi. Medication (prescribed vs. dispensed)
 - vii. Lab results

- viii. Imaging results. Storage of images considered out of scope at this time.
- b. Medication profile, Lab results and imaging results could optionally be dealt with separately as longitudinal profiles.

Personal Details

- Name (first name and surname)
- Physical + postal address
- Postal code
- Telephone numbers
- ID number
- Next of kin details
- Guardian details
- Date of birth
- Insurer / med aid number
- Insurer / med aid name
- Employment
- Level of education
- Gender
- Religion
- Marital status
- Number of children
- Unique patient identifier (If not the ID number)
- Nationality
- Blood groups
- Allergies
- Current chronic conditions
- Current medication
- Current medical conditions
- Current practitioner / GP
- Immunisation status
- Disability status
- Pregnancy status (currently pregnant or taking contraceptives)
- Smoking indicator

Past Medical History

- Diagnosis (multiple)
- Treatments and procedures
- Medications
- Free text field
- Institutions (hospital / clinic etc)
- Practitioner
- Dates (of treatment or entry/ exit into an institution/ death)
- Encounter outcomes
- Categorisations
- Previous blood results history + continuous updates
- Test results
- Vaccinations
- Confidentiality indicator

Glossary:

Audit Trail: A programme that records access and/or action that

occurs in a computer record by logging the user

identification, recording date and time of access and

action carried out.

Backup: The creation of a second copy of records or information in

case the original is lost or damaged.

Clinician: All health professionals who provide care directly to a

patient - doctors, nurses, physical therapists,

occupational therapists, etc.

Confidentiality: The act of limiting disclosure of private information.

Consumer: A recipient of healthcare such as the patient.

Cost-benefit Analysis: A comparison of costs against benefits to determine the

long-term value of the proposed system.

Cryptography: Mathematical functions that transform intelligible data into

seemingly unintelligible data and back again.

Data: A collection of numbers, characters or facts that are

gathered according to some perceived need for analysis.

Database: A file structure that supports the storage of data in an

organised fashion and allows data retrieved as

meaningful information.

Data Integrity: The ability to collect, store and retrieve correct, complete

and current data so that it is available to authorised users

when needed.

Data Set: A group of data elements relevant for a particular use.

Data Structure: How data is stored, as in a file, a database, a data

repository, etc.

Decision-support

Systems:

Programs that organise information to aid decision-

making related to patient care or administrative issues.

Digital Signature: A scanned image of a written signature.

Document Imaging: Involves scanning paper records to computer disks or

other media to facilitate storage and handling.

Electronic Signature: A means to authenticate a computer-generated document

through a code or digital signature that is unique to each

authorised system user.

Encryption: The use of mathematical formulas to code messages.

Evidence-based

medicine:

Clinical decision support based on evidence of best

practice.

Extranet: A network that sits outside the protected internal network

of an institution by outsiders and uses Internet software

and communication protocols for use by suppliers or

customers.

Goal: An open-ended statement describing what is to be

accomplished.

Go-live: The process of starting to use the information system.

Health Information: Healthcare data that has been organised into a

meaningful format.

Health Information

System:

A system that integrates data collection, processing, reporting, and the use of the information necessary for improving health service effectiveness and efficiency through better management at all levels of health services (WHO 2004).

Health Level 7 (HL7):

A standards institution which develops standards for the exchange of clinical data between information systems by means of an extensive set of rules that apply to all data sent.

The standards are also referred to as HL7. Health Practitioner: See 'Clinician'.

Infostructure: The underlying framework of a computer system that

processes data and information.

Integration: The process by which different information systems are

able to exchange data in a fashion that is seamless to the

end user.

Interface: A computer system that tells two different systems how to

exchange data.

Interoperability: The ability for systems to work together.

Intranet: A computer network using Internet protocols and

technologies to facilitate collaborative data sharing.

Longitudinal: To reflect the entire history of an individual across his or

her lifetime, including data from multiple users.

Mapping: The process where terms defined in one system are

associated with comparable terms in another system.

Messaging Standards: Standard protocols that assist in the exchange of data

between two separate systems.

Multimedia: Presentations that combine text, voice or sound, still or

video images as well as supporting hardware and

software.

Network: A combination of hardware and software that allows

communication and electronic transfer of information

between computers.

Optical Character

The technology of reading text by electronic means and

Recognition (OCR):

converting it to data.

Password: An alpha-numeric code required for access and use of

some computers or information systems as a security

measure against unauthorised use.

Personal Health

A record maintained by or for direct patient access.

Record:

Point-of-Care System: A computer system that captures data at the location

where healthcare is provided.

Practitioner: Healthcare professional such as doctor, nurse, physical

therapist etc.

Providers: Care givers – a term used to refer to clinicians or the

healthcare institution providing healthcare.

Real Time: The processing of data that takes place at the time an

event occurs.

Retention: The maintenance and preservation of information.

Smart Card: A storage device resembling a plastic credit card

containing patient information.

SNOMED: Systematized Nomenclature of Human and Veterinary

Medicine – a comprehensive clinical vocabulary.

Standard: A specimen or specification by which something may be

tested or measured.

Strategic Planning: The development of a comprehensive long-range plan for

guiding activities and operations of an institution.

Structured data: Data that follows a prescribed format.

Unique Patient

Identifier:

A single, universal identifier for patient health information

that ensures availability of all data associated with a

particular person.

Unstructured Data: Data that does not follow a prescribed format such as

may be seen in narrative recording.

Validity: The extent to which data measures what it purports to

measure.

Voice Recognition: Technology using voice patterns to allow computers to

record voice and automatically translate it into written

language in real time.

Work-flow: The sequence of actions applied to a process to achieve

a result; typically crosses institutional units or different

steps taken by the same user.

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